Centre for the Advancement of Health Innovations (CAHI)

MaRS EXCITE

Excellence in Clinical Innovation and Technology Evaluation

Monday, April 16th, 2012

The Old Mill Inn and Spa, Toronto ON

Leslie Levin MB, MD, FRCP (Lon), FRSPC
Head, Medical Advisory Secretariat, Health Quality Ontario
Chief Scientific Officer, MaRS EXCITE
Professor of Medicine, University of Toronto
The Current State of HTA

Ontario’s post-market health technology assessment is world-class, but post-market Health Technology Adoption (HTA) has inherent limitations.

**Why?**

Limited *crosstalk* during the development process can mean *greatly protracted timelines* before new technologies are adopted.
Life-Cycle Diffusion Curve

- Steady State
- Evidence & Uncertainty
- Diffusion
- Inflection Point [Post-Market]
- R & D

Agents:
- MAS/ OHTAC
- CADTH
- NICE
- MSAC
- BCBS
- CMS
## EXCITE Moves Evaluation Upstream addressing questions early on

<table>
<thead>
<tr>
<th><strong>Device Development</strong></th>
<th><strong>Device Manufacture and Testing</strong></th>
<th><strong>Device Licensing</strong></th>
<th><strong>Adoption (OHTAC, MOHLTC)</strong></th>
<th><strong>Uptake</strong></th>
<th><strong>Use and monitoring</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-clinical</td>
<td>Clinical</td>
<td>Government licensing</td>
<td>Physician reimbursement</td>
<td>Introduction to/acceptance by healthcare professionals</td>
<td>Track long term effectiveness and safety</td>
</tr>
<tr>
<td>- Design</td>
<td>- Effectiveness and safety testing in patients</td>
<td>- Supply chainingy Infrastructure</td>
<td>- Economic benefit</td>
<td>- Ease of use</td>
<td>- Ease of use</td>
</tr>
<tr>
<td>- Prototyping</td>
<td></td>
<td>- Based on:</td>
<td>- Relevance</td>
<td>- Training</td>
<td>- Training</td>
</tr>
<tr>
<td>- Effectiveness</td>
<td></td>
<td>- Economic benefit</td>
<td>- Magnitude of effect</td>
<td>- Preferences</td>
<td>- Preferences</td>
</tr>
<tr>
<td>and safety testing</td>
<td></td>
<td>- Relevance</td>
<td>- Disruptive potential</td>
<td>- Cost</td>
<td>- Cost</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Magnitude of effect</td>
<td>- Effectiveness</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Disruptive potential</td>
<td>- ?Field study</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Pre-Market**
- Device Development
- Device Manufacture and Testing
- Device Licensing

**Post-Market**
- Adoption (OHTAC, MOHLTC)
- Uptake
- Use and monitoring

**Physician licensing**
- Physician reimbursement
- Supply chainingy Infrastructure
- Based on:
  - Economic benefit
  - Relevance
  - Magnitude of effect
  - Disruptive potential
  - Effectiveness
  - ?Field study

**Introduction to/acceptance by healthcare professionals**
- Ease of use
- Training
- Preferences
- Cost

**Track long term effectiveness and safety**
Building on current best practice with a catered prioritization, selection and evaluation process for the most disruptive technologies
OHTAC *recommendations* based on:

- **Relevance** to the needs of the health care system
- **Disruptive potential** (e.g. promise of substantially better clinical outcomes, substantially lower system costs to incumbent approaches)
- Opportunities to **identify obsolescence** for existing technologies
- Estimated **magnitude of effect** for the target population
- **Stage of readiness** of the technology and how effectively it can be evaluated
EXCITE Board selection/prioritization based on:

- **Relevance** to the needs of the health care system
- **Disruptive potential** (e.g. promise of substantially better clinical outcomes, substantially lower system costs to incumbent approaches)
- Opportunities to **identify obsolescence** for existing technologies
- Estimated **magnitude of effect** for the target population
- **Stage of readiness** of the technology and how effectively it can be evaluated
- Potential **economic benefit** to Ontario (e.g. job creation, investment in R&D)
- **Feasibility**
- **Capacity**
Key Steps in the EXCITE Process

Building on current best practice with a catered prioritization, selection and evaluation process for the most disruptive technologies

SME and MNE Technologies

Apply

Review by OHTAC Subcommittee

Prioritization and Selection by EXCITE Board (with scientific input on feasibility)

Evaluation by EXCITE Methodological Centres

Proposals are drafted by the Methodological Centres and:
- Reviewed by a QA team for safety and other quality issues
- Discussed by Scientific Collaborative
- Approved by the EXCITE Board
- Accepted by the Applicant
Advantages of enrolling in EXCITE

- Access to a vast network of expertise
- Single harmonized process – one-stop shopping
- Feedback from stakeholders and the health system
- Designed to anticipate and mitigate challenges and risks associated with regulatory approval, adoption, and market penetration.
- Decreased time to market and increased market exclusivity
- Increased revenue potential
- Increased investor confidence
Some Key Success Predictors

- Turn-key operation
- Neutral space at MaRS
- Fully supported by government
- Funded by industry through MaRS
- Oversight of quality, conflicts of interest, objectivity to provide credibility and relevance by OHTAC
- Allows health system to prepare infrastructure and terms of adoption
- Allows industry and health system to horizon scan together
The EXCITE Opportunity

A novel approach that matches health technology innovation with patient needs and health system priorities

Position Ontario as Global Destination for Pre-Market Evaluation

Foster Enhanced Industry/Regulatory/Healthcare Sector Dialogue

Enable Early End-user Engagement, leading to Better Products

Accelerate Commercialization and Adoption

Improve Patient Outcomes
EXCITE Management Board

MaRS Board

EXCITE Chief Scientific Officer

Industry: MEDEC, HTX

Government: MOHLTC, MEDI

Health System: OHTAC

Academia: CAHO
EXCITE Scientific Collaborative

Current evaluation leaders coming together in the pre-market space

- McMaster University
  - Program for the Assessment of Technologies in Health (PATH)
  - Clinical Trials Methodology Group (CTMG)
  - Ontario Clinical Oncology Group (OCOG)
- University of Toronto
  - Toronto Health Economics and Technology Assessment (THETA) Collaboration
  - Centre for Innovation in Complex Care (CICC)
- University Health Network - Health Technology Safety Research Team (HTSRT)
- London Health Sciences Centre - Canadian Surgical Technology and Robotics Team (CSTAR)
- Ottawa Hospital Research Institute (OHRI)
- St. Michael’s Hospital – The Li Ka Shing Knowledge Institute (LKSIgn), ARC
- The Council of Academic Hospitals of Ontario (CAHO)
- Institute for Clinical Evaluative Sciences (ICES)
EXCITE Collaboration

September 7, 2011 meeting at MaRS with 29 representatives from academia, the health system, government, and industry
MaRS EXCITE – now underway

Excellence in Clinical Innovation and Technology Evaluation

- **September 7** – MaRS convened a full-day meeting of key EXCITE stakeholders. Industry and government participants from MEDEC, HTX, MOHLTC and MEDI joined scientists for the morning overview of EXCITE. In the afternoon, 15 representatives from 8 academic health centres and CAHO began to work through the methodology for conducting pre-market technology evaluations.

- **November 14** – Management Board to initiate a Call for Innovation to Industry

- **December 20** – Industry medical technology Applications Deadline
MaRS EXCITE – now underway

*Excellence in Clinical Innovation and Technology Evaluation*

- **January 3:** OHTAC Subcommittee reviewed the applications
- **January 11:** MaRS EXCITE Management Board prioritized **4 technologies** for inclusion in the EXCITE Pilots (2 MNEs and 2 SMEs)
- **January 26:** Technologies were assigned to participating Methodological Centres for evaluation
- **February:** Initial meetings between Methodological Centres and prioritized technology applicants for **protocol design**
- **March – April:** Approve protocols and set pricing
- **Pilot Evaluations** to commence upon receipt of necessary approvals (e.g. REB, ITA). Evaluations anticipated to take 12-24 months to complete; quarterly reporting to industry, the EXCITE Management Board, and MaRS Board
- **2nd Call for Innovation** as early as summer 2012 (anticipated)
For More Information

Please visit:

http://excite.marsdd.com

Or contact:

Monique Albert, Manager, MaRS EXCITE
416.673.8464
malbert@marsdd.com