MaRS Excellence in Clinical Innovation and Technology Evaluation (EXCITE)

EXCITE provides health technology innovators with a holistic view and streamlined approach to the go-to-market process, anticipating and mitigating common barriers. EXCITE is designed to improve the odds of a breakthrough health technology’s success—particularly with health system adoption and uptake.

A catalyst for better health technologies

EXCITE unifies Ontario’s best-in-class approach to medical technology testing, bringing together a broad spectrum of research under one harmonized platform based on relationships brokered with academic health research facilities across the province. Innovators get feedback early in the development process, when there is still time to make any required adjustments to meet the needs of the medical system.

A pre-market, single-evaluation approach

EXCITE’s approach generates data to support both regulatory (for example, Health Canada in Canada) and reimbursement (for example, the Ontario Health Technology Advisory Committee and the Ministry of Health and Long-Term Care in Ontario) applications. Clear and appropriate evidence increases the probability of uptake in Canada and beyond, helping to get new and useful technologies to clinicians faster for better patient outcomes.

Features

• Presents an integrated evaluation approach that provides companies with valuable evidence and business requirements—key information for regulatory reviews, reimbursement reviews and competitive positioning.

• Enables access to health system stakeholders and testing in world-class research centres within one harmonized platform.

• Provides a competitive advantage because more meaningful testing and feedback is delivered early in the product lifecycle when re-development is still possible.

• Addresses the full spectrum of possible barriers to adoption through additional offerings, including patient preference analyses, human factors assessments and programs to train end users, as well as longitudinal registry studies to evaluate the performance of the technology (incl. safety) once adopted by the health system.

• Participation in EXCITE can be a powerful tool for raising capital, as the process flags high-potential technologies that are useful to the health system and more likely to receive reimbursement approvals; funders/investors can have more confidence that investments will pay off.

• A first of its kind, EXCITE is the only harmonized pre-market program that provides the testing and feedback required for OHTAC to assess health technologies; removes the requirement for post-market, evidence-based analysis.
The EXCITE Core Evidentiary Bundle

An EXCITE methodological centre will conduct each evaluation in collaboration with leading academic hospitals and health centres. EXCITE’s Core Evidentiary Bundle comprises:

- a field evaluation/clinical trial as an assessment of a technology’s clinical utility (from the perspective of the health system) and safety and efficacy (meeting criteria for licensing in Canada and, where requested, targeted foreign markets);

- a systematic review of competing technologies to assist in determining the appropriate market niche and benchmarks from the perspective of the health system; and

- an economic analysis, including a cost-effectiveness and budget-impact analysis from the perspective of the health system.

Together, these provide the minimum amount of data needed to inform an Ontario Health Technology Advisory Committee (OHTAC) review through the EXCITE process and support a Health Canada licensing application. EXCITE will provide additional data required by other licensing bodies (for example, the FDA) if requested by applicants.

Additional evaluations (available upon request)

In addition to the EXCITE Core Evidentiary Bundle, industry applicants can request investigations into areas that may affect market uptake, as is appropriate for their specific medical technology. These options include:

- analyses of technology usability and human factors;

- an analysis of uptake efficiency;

- a comprehensive education program for training end-users in the use of the technology;

- the development of a registry to track post-adoption effectiveness and long-term safety outcomes; and

- an assessment of patient preferences.

To learn more or to apply, please visit us online: excite.marsdd.com