
PROGRAM GUIDE: ACCELERATING INNOVATIONS INTO CARE (AICE) – MARKET ACCESS

PROGRAM OVERVIEW

Background

Global health care expenditures are projected to increase at an annual rate of 5.4 percent between 2017-2022, from USD \$7.724 trillion to USD \$10.059 trillion.¹ In Alberta, approximately \$2.4M is spent every hour on healthcare – nearly 40% of the provincial budget.² Furthermore, growth in provincial healthcare spending per capita has been outpacing growth in GDP per capita by roughly 2% on average between the years of 1996 to 2016,³ which suggests that sustainability has been a persistent issue. An aging population, a higher prevalence of chronic disease, and a higher demand for multidisciplinary care sites suggest that the trend of rising healthcare costs will not be slowing down. The sustainability of the healthcare system will depend on innovations that can enhance the efficiency, safety, quality and productivity of healthcare delivery.⁴

With this challenge comes global opportunity, and innovative small to medium sized enterprises (**'SMEs'**) are a key component of success. The advent of digital and data-enabled technologies has the potential to offer patient-focused, clinical and operational solutions that will form the foundation of a more affordable, accessible, and high-quality health care system. However, SMEs face barriers when seeking opportunities to validate innovations with clinicians, patients, care providers and potential investors. In addition, health system partners often lack resources necessary for testing new technologies within the context of existing care pathways. In order to facilitate adoption of promising health innovations, meaningful partnerships must be created and supported among all stakeholders involved.⁵

¹ Allen, Stephanie (2019) *2019 Global Health Care Outlook*. Deloitte. Retrieved from: <https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-health-care-sector-outlook.html>

² De Cillia, Brooks (March 25, 2018) *Alberta spends \$2.4M an hour on health care — here's what's being done to reduce it*. Retrieved from: <https://www.cbc.ca/news/canada/calgary/alberta-spends-2-4m-an-hour-on-health-care-here-s-what-s-being-done-to-reduce-it-1.4589048>

³ Canadian Institute for Health Information. *Health Expenditures in the Provinces and Territories: Provincial and Territorial Chartbook, 2017*. Ottawa, ON: CIHI; 2017 (constant 1997 dollars)

⁴ The Conference Board of Canada (November 2017) *Canadian Conference Board of Canada's Council for Innovation Procurement in Healthcare*. Retrieved from: https://www.conferenceboard.ca/docs/default-source/network-public/nov2017_cip_brochure_web.pdf?sfvrsn=d384a7e5_2

⁵ MacNeil, M. et al (2019) *Enabling health technology innovation in Canada: Barriers and facilitators in policy and regulatory processes*. Elsevier. Retrieved from: <https://www.sciencedirect.com/science/article/pii/S0168851018305396>

Program Details

AICE-Market Access is designed to catalyze health innovations that face an evidentiary hurdle in achieving market access. The Program supports SMEs and Real-World Testing Sites (“**Testing Sites**”) in carrying out implementation projects or clinical trials of innovative health technologies. Alberta Innovates will contribute up to \$300,000 CAD of funding to support approved Projects over a maximum term of 24 months. Successful Projects are designed to generate evidence that will facilitate broad market adoption and diffusion of the innovation, based on evidentiary needs as expressed by regulatory agencies and/or key adoption decision makers. Each Project must align with at least one of the priority areas, be ready for clinical/real world-testing, and be accompanied by a compelling business model demonstrating positive impact for Alberta.

The three research and innovation priority areas for the AICE-Market Access Program are:

- **Data-Enabled Innovation** – technology that supports the creation, amalgamation and analysis of complex data sets to improve decision making;
- **Digital Tech for Business Transformation** – technology that collects, senses, measures, connects, and distributes information to improve health outcomes or realize health system economic value; or
- **Innovative Production and Distribution** – technology or processes that enhance, accelerate or alter the way health care is delivered.

Successful Projects will require close collaboration between the SME (“**SME Applicant**”) and Testing Site (“**Testing Site Applicant**”). The partnership between the SME Applicant and Testing Site Applicant must be established prior to applying for AICE –Market Access. Innovative SMEs or Testing Sites who are having difficulty locating a partner are encouraged to contact Alberta Innovates for advisory support.

AICE – Market Access provides a platform of engagement between innovative small to medium sized enterprises (SMEs) and Real-World Testing Sites (‘Testing Sites’). AICE – Market Access facilitates market adoption and diffusion of health innovations through the generation of clinical and operational evidence.

HOW THE PROGRAM WORKS

Eligibility

Each Project funded through AICE – Market Access must involve an SME Applicant and a Testing Site Applicant. **At least one party – the SME Applicant or Testing Site Applicant – must demonstrate a significant legal and physical presence in Alberta.**

(a) SME Applicant Eligibility Criteria – To qualify as an SME Applicant, the following criteria is required:

- be a for-profit SME;
- demonstrate the relationship between the SME Applicant and Testing Site Applicant does not create a conflict of interest;

- meet the following definition of an SME: a private company with fewer than 500 full-time employees and less than \$50,000,000 annual gross revenues;
- be a legal entity with up to date corporate filings*:
 - incorporated in Alberta; or
 - incorporated in another jurisdiction; or
 - a General Partnership, Limited Partnership or Limited Liability Partnership registered in Alberta; or
 - a General Partnership, Limited Partnership or Limited Liability Partnership registered in another jurisdiction;
- possess a health innovation that is ready for clinical/real-world testing, defined as:
 - regulatory approved (Health Canada, FDA or equivalent); or
 - holding an Investigational Testing Authorization ([ITA](#)), Clinical Trial Application ([CTA](#)) or equivalent; or
 - not requiring regulatory approval, but having a high degree of technology readiness (TRL 7 to 9); and
 - possess all other necessary certification and/or privacy approvals; and
- be in good financial standing with Alberta Innovates and its subsidiaries InnoTech Alberta and C-FER Technologies.

**Please note, Alberta Innovates will perform a corporate search and may also seek bankruptcy and litigation searches.*

(b) Testing Site Applicant Eligibility Criteria – to qualify as a Testing Site Applicant, the following criteria is required:

- be a for-profit, not-for-profit organization, or government affiliated entity;
- demonstrate the relationship between the Testing Site Applicant and SME Applicant does not create a conflict of interest;
- be a legal entity:
 - incorporated in Alberta; or
 - incorporated in another jurisdiction; or
 - a registered not-for-profit with or without charitable status in Alberta; or
 - a registered not-for-profit with or without charitable status in another jurisdiction; and
- possess the resources and infrastructure required for supporting the proposed implementation Project; and
- be in good financial standing with Alberta Innovates and its subsidiaries InnoTech Alberta and C-FER Technologies.

(c) Project Eligibility Criteria

To qualify for funding all Projects must:

- include at least one testable business hypothesis based on evaluation criteria provided by key purchasing decision makers OR include a testable clinical hypothesis that will support the regulatory approval process;
- present sound methodology that will test the business or clinical hypotheses and inform any barriers to adoption;
- include key Project milestones based on metrics and deliverables, stepped with critical “go/no-go” decision points;
- be completed within the 24-month term; and
- submit to other criteria that Alberta Innovates may develop from time to time.

Program Objectives and Performance Measurement

AICE – Market Access aims to achieve health, economic and health system economic gains for Alberta. The Program provides a platform of engagement between innovative SMEs and Testing Sites. AICE – Market Access facilitates market adoption and diffusion of health innovations through generation of market-driven evidence.

Over the life of a Project, Alberta Innovates employs an active project management philosophy, regularly monitoring performance and supporting the SME Applicant and Testing Site Applicant to reach their objectives. Funding is tied to outcomes and achievement of results. For this reason, Alberta Innovates funds on a milestone completion basis. This means the SME Applicant and Testing Site Applicant are expected to submit a Progress Report before Alberta Innovates advances the next tranche of funds.

Once Projects are completed, Alberta Innovates continues to monitor performance for five (5) years to accurately evaluate the economic, social and environmental benefits realized for the province.

All Investment Agreements outline performance indicators tracked over the course of the Project and the responsibilities of the SME Applicant and Testing Site Applicant to report on outcomes subsequent to completion of the Project.

Alberta Innovates has a common set of performance metrics it monitors, both at the individual Project level and for the aggregate Program. These are highlighted on the next page.

Program Objectives and Performance Metrics



SME APPLICANT OBJECTIVES

Acquire evidence through real-world implementation projects that supports broad market adoption and diffusion

Build connections within the health innovation ecosystem

Achieve progression of technology, clinical, business and regulatory readiness

TESTING SITE APPLICANT OBJECTIVES

Build capacity for adopting promising health innovations

Improve competitiveness in a rapidly shifting health care environment

Build connections within the health innovation ecosystem

SHORT TERM



PERFORMANCE INDICATORS

of patents

of publications

of health economic studies completed

of clinical trials completed

of international presentations and abstracts

progression of the innovation's technology, clinical, business and regulatory readiness

LONG TERM



PROGRAM PERFORMANCE INDICATORS

of partnerships formed

of projects completed

of SMEs with improved understanding of health system market access

of regulatory approved innovations

SME investment and/or revenue growth

of new jobs created

of procurement events (revenue (\$) for products directly related to AICE-Market Access)



ALBERTA IMPACTS

Economic and Ecosystem

Health innovation ecosystem development

Health System Economic Value

Improve efficiency, effectiveness, accessibility, and safety

How Funding Works

(a) Project Funding

Alberta Innovates' Investment for successful Projects will be 50% of the total eligible Project Costs up to a maximum of \$300,000 per Project. The balance of total eligible Project Costs must be provided in the form of cash and/or in-kind contributions (the "**Contribution**") from the SME Applicant, the Testing Site Applicant, and/or another grant funding program. However, the SME Applicant must contribute at least 25% of the total eligible Project Costs. The Testing Site Applicant is not required to provide a minimum contribution of the total eligible Project Costs.

Alberta Innovates' Investment is dispersed upon receipt and approval of a Progress or Final Report, over the maximum twenty-four (24) month term.

(b) In-Kind Contributions

In-kind Contributions are defined as the non-cash provision of goods or services by either the SME Applicant or Testing Site Applicant valued in monetary terms according to rules agreed upon beforehand by all parties, and within the purview of generally accepted accounting principles. The value placed on In-kind Contributions may not exceed the fair market value of the product or service.

In-kind Contributions may include provision of any products or services deemed to be Eligible Expenses as outlined in the next section. They are regarded as necessary to carry out the tasks and achieve the goals and milestones of the Project as put forward in the Project methodology. These costs would have to be paid for if they were not provided by either party. In-kind resources will only be recognized as an Eligible Contribution where the costs incurred are directly attributable to the Project and easily auditable.

Alberta Innovates will contribute up to \$300,000 CAD of 1:1 matching funding to support approved Projects over a maximum term of 24 months.

(c) Eligible and ineligible expenses

Alberta Innovates only funds reasonable costs incurred, subsequent to a signed Investment Agreement between Alberta Innovates, the SME Applicant and the Testing Site Applicant. Any costs incurred prior to the signing of the Investment Agreement, or costs greater than market prices are deemed ineligible. Costs must be incurred between Arm's Length entities.

The chart on the next page provides a high-level summary of eligible and ineligible expenses.

Summary of Eligible and Ineligible Expenses

Category	Eligible Expenses	Ineligible Expenses
Salaries and Benefits	<ul style="list-style-type: none"> ✓ Salary and benefits for staff, students or contractors who are specifically working on the Project 	<ul style="list-style-type: none"> ✗ Salary, consulting fees or honoraria support for physicians, academic faculty members or company executives/senior management involved ✗ Salary and costs of administrative and/or indirect support staff ✗ Salary and costs associated with proposal development
Travel (up to 5% of Total Project Costs)	<ul style="list-style-type: none"> ✓ Project specific out-of-pocket travel expenses for work at the test-site that is directly associated with the Project ✓ Other reasonable out of pocket expenses for field work and dissemination activities 	<ul style="list-style-type: none"> ✗ Costs to cover conference fees, travel, hotels and food to attend events or meetings unrelated to Project ✗ Entertainment expenses, gifts, awards and alcoholic beverages ✗ Reimbursement for airfare purchased with personal frequent flyer point programs ✗ Commuting costs between residence and place of employment
Equipment, Materials and Supplies	<ul style="list-style-type: none"> ✓ Cost of equipment, materials and supplies needed to support Project if they are not already provided by the SME Applicant or Testing Site Applicant 	<ul style="list-style-type: none"> ✗ Cost or rental equivalents exceeding accepted values had the equipment been donated or sold ✗ Development costs incurred prior to the start of the Project ✗ Depreciation costs associated with equipment donated to the Project
Software, New Technologies and Databases	<ul style="list-style-type: none"> ✓ Costs of purchasing licenses needed for the Project, if not already provided by the SME Applicant or Testing Site Applicant ✓ Development costs for ancillary technology related to the Project ✓ Costs of collecting, de-identifying and archiving data that is critical to the success of the Project 	<ul style="list-style-type: none"> ✗ Cost of new software and technologies that go outside the scope and/or duration of the Project

Use of Facilities

- ✓ Meeting rooms, space or facilities for which a fee is charged by the Test Site Applicant, SME Applicant or sub-contractor
- ✓ Rental costs for specialized equipment needed
- ✗ Indirect or overhead costs associated with facilities (utilities, repair of office furniture, admin fees, insurance, telephones, etc.) that do not contribute directly to the Project
- ✗ Revenues that are forgone by the contributor because of participation in the Project and related programs

Other Expenditures

- ✓ Other expenditures which are directly associated with meeting the deliverables and milestones in the Project
 - ✗ Other expenditures which are not directly associated with meeting the deliverables and milestones set out in the Project
 - ✗ Other expenditures which are incurred well outside the scope and/or duration of the Project
 - ✗ Indirect or overhead costs of any kind
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HOW TO APPLY



STEP 1 Intake Form

Interested SMEs and Testing Sites who meet the Program Eligibility requirements defined earlier are encouraged to submit an Intake Form.

Prospective Applicants are free to contact the AICE Program Manager with any questions or concerns prior to submitting the Intake Form.



STEP 2 Pre-Application Meeting

It is recommended to hold a pre-application meeting between the SME Applicant, Testing Site Applicant, and Alberta Innovates.

This meeting will ensure that the SME Applicant, Testing Site Applicant and Alberta Innovates are aligned in terms of the desired Project objectives, deliverables and outcomes.



STEP 3 Application

Applications are accepted at any time.

Applications will be reviewed by external reviewers with relevant commercialization and clinical expertise

EVALUATION PROCESS

During the different phases of the Program, Alberta Innovates leverages internal staff and external expert reviewers to evaluate the Applications submitted. Alberta Innovates evaluates promising innovations based on criteria related to the innovation opportunity, Project implementation, business readiness, and potential for Alberta impact.

Alberta Innovates retains the sole right to determine the evaluation process and does not disclose the names of its external reviewers to ensure their objectivity and impartiality. All external parties are subject to both confidentiality and conflict of interest policies set by Alberta Innovates.

An Applicant whose Application is declined by Alberta Innovates may, on a one-time basis, re-apply to Alberta Innovates to address and correct any deficiencies or issues. Where a shareholder of an SME owns 51% of any other SME, as indicated by the corporate search, the SMEs will be considered one in the case of a re-application where the Project or technology is the same.

The assessment criteria for AICE – Market Access and all investment decisions are at the sole discretion of Alberta Innovates.

TERMS AND CONDITIONS

This Program Guide is intended as a high-level overview of the Program. It provides interested Applicants with a roadmap of what to expect over the lifecycle of an AICE-Market Access Project, from the announcement of the program, through the Application stage, during the Project and post-completion. Should you have any questions about this guide or what is expected, please contact Alberta Innovates. Please be aware Alberta Innovates may modify this guide from time to time in keeping with any changes to the program.

Alberta Innovates will only correspond in writing and provide copies of the Application to the persons named in the application form as the one authorized to speak for the SME Applicant and Testing Site Applicant respectively.

Once we have evaluated and approved an Application for funding, Alberta Innovates will require both the SME Applicant and Testing Site Applicant to sign our standard form Investment Agreement. The Investment Agreement sets out in detail the roles, responsibilities and obligations of the various Parties to ensure a successful Project. Alberta Innovates will not provide any funding until the Investment Agreement has been signed by all Parties.

Alberta Innovates will only fund Applicants who have satisfied all eligibility criteria. Meeting the eligibility criteria does not guarantee access to funding, and all funding decisions will be made by Alberta Innovates at its sole discretion.

DIVERSITY, EQUITY, AND INCLUSION (DEI)

We believe the Alberta research and innovation (R&I) ecosystem is stronger and more sustainable when it is broadly reflective of the overall diversity of our community. Alberta Innovates strives to ensure all interested and qualified parties have an equitable opportunity to participate and contribute.

Historically, there have been a number of groups/populations that have been under-represented in the Alberta R&I landscape including:

- Women entrepreneurs/researchers;
- Indigenous entrepreneurs/researchers;
- Remote/small community entrepreneurs/researchers; and
- New immigrant entrepreneurs/researchers.

We are guided by the principles of:

- Diversity – both internal and external participants to our processes are comprised of a varied composition of demographics;
- Equity – our processes support equal access across all demographics; and
- Inclusivity – our processes proactively work to include underrepresented segments of the R&I landscape.

Accordingly, as part of its commitment to Diversity, Equity and Inclusion (DEI), Alberta Innovates will request Applicants' permission to:

- Collect data in the Application on a voluntary basis to better understand diversity;
- Provide Application navigation support to Applicants from under-represented groups; and
- Integrate a DEI focus into its due diligence processes including striving to have diverse review committees to foster unbiased decision making.

CONTACT INFORMATION

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Version 2.0 – November 26, 2019