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## PROGRAM GUIDE:

# Accelerating Innovations into CarE – Market Access Program (AICE-MAP)

## 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.<sup>1</sup> In Alberta, approximately \$2.4M is spent every hour on healthcare – nearly 40% of the provincial budget.<sup>2</sup> 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,<sup>3</sup> 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.<sup>4</sup>

With this challenge comes global opportunity, and Alberta-based small to medium sized enterprises (**'SMEs'**) are a key component of success. The opportunities are boundless for Alberta's health technology and life sciences SMEs to be successful on a global scale – simultaneously delivering economic value to Alberta and health impact at home and abroad. However, SMEs face barriers when seeking to validate innovations with regulators, clinicians, patients, care providers and potential investors. Health system partners often lack resources necessary for validating new technologies in the context of existing care pathways. A platform for meaningful partnership will help support stakeholders in generating the evidence needed for adoption of promising health innovations.

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<sup>1</sup> 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>

<sup>2</sup> 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>

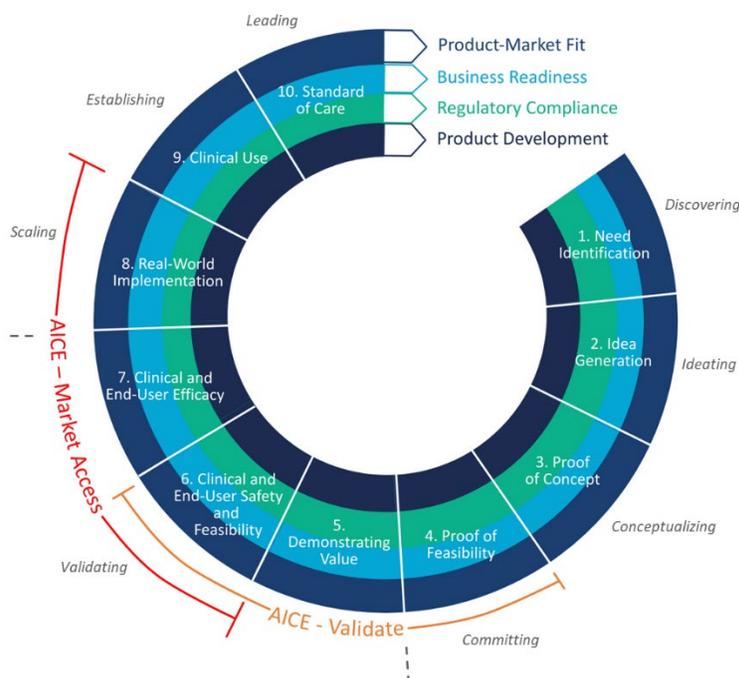
<sup>3</sup> Canadian Institute for Health Information. *Health Expenditures in the Provinces and Territories: Provincial and Territorial Chartbook, 2017*. Ottawa, ON: CIHI; 2017 (constant 1997 dollars)

<sup>4</sup> 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](https://www.conferenceboard.ca/docs/default-source/network-public/nov2017_cip_brochure_web.pdf?sfvrsn=d384a7e5_2)

## Program Details

Through the Accelerating Innovations into Care (AICE) programs, Alberta Innovates supports innovators in progressing towards commercialization across the four key domains of the Health Innovation Cycle (see figure below). The AICE-Market Access Program (AICE-MAP) is specifically designed to catalyze health innovations that face evidentiary hurdles in achieving market access including clinical safety, efficacy and real-world evidence.

### HEALTH INNOVATION CYCLE<sup>5</sup>



The AICE – Market Access Program supports SMEs and clinical or real-world testing sites (“**Testing Sites**”) in carrying out implementation projects, feasibility studies 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 key evidence that will facilitate commercial progression and market adoption of the innovation. Each Project must align with at least one of the innovation priority areas, be ready for clinical/real world-testing, and be accompanied by a compelling business model demonstrating strong potential for positive economic impact in Alberta.

The three innovation priority areas for AICE-MAP are:

- **Data-Enabled Innovation** – technology that supports the creation, amalgamation and analysis of complex data sets to improve decision making;

<sup>5</sup> Adapted from the Consortia for Improving Medicine with Innovation & Technology’s Guidance and Impact Tracking System. <https://www.gaits.org/ja/>.

- **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 and Testing Site. 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.

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*The AICE – Market Access Program accelerates health innovations through the Health Innovation Cycle – from initial clinical safety and feasibility to real-world implementation.*

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## HOW THE PROGRAM WORKS

### Eligibility

Each Project funded through AICE-MAP must involve an SME Applicant and a Testing Site Applicant.

**Note:** the SME must be Alberta-based, while the Testing Site may be located outside of Alberta.

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

- be a for-profit SME;
- demonstrate the relationship between the SME and Testing Site does not create a conflict of interest;
- be an Alberta-based company with an Albertan footprint, which is determined by the following: significant physical and corporate operational presence in Alberta, appropriate Alberta ownership, and discernable intent that operational benefits will flow primarily within the province of Alberta;
- 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 federally or in another jurisdiction AND extra-provincially registered in Alberta; or
  - a General Partnership, Limited Partnership or Limited Liability Partnership AND registered in Alberta; and
- be able to demonstrate completion or near completion of all milestones up to and including the Demonstrating Value stage of the Health Innovation Cycle. *For more details, see the [Health Innovation Cycle Checklist](#).*

- 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 (or an ITA/CTA or equivalent), but having a high degree of technology readiness (TRL 6 to 8) and design freeze for base technology; and,
  - possess all other necessary certification and/or privacy approvals
- 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, the following criteria is required:

- be a for-profit, not-for-profit organization, post-secondary institution or government affiliated entity;
- demonstrate the relationship between the SME and Testing Site 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
- 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 hypothesis related to the health innovation that is informed by key adoption influencers;
- propose 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

The AICE-Market Access Program aims to achieve health, social and economic gains for Alberta. The Program accelerates the development of health technology-based innovations. Specifically, it seeks to:

- (i) Support the accelerated testing and development of digital health innovations through the Health Innovation Cycle.
- (ii) Cultivate a high performing R&I ecosystem by contributing to a diversified economy and enhancing the health of Albertans.

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*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.*

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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 Applicant to report on outcomes subsequent to the completion of the Project. You'll find a sample Investment Agreement on our [website](#).

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 accelerates market adoption and diffusion

Build connections within the health innovation ecosystem

Achieve progression along the Health Innovation Cycle, including the domains of Product-Market Fit, Business Readiness, Regulatory Compliance, and Product Development

## TESTING SITE APPLICANT OBJECTIVES

Build capacity for adopting promising health innovations

Improve competitiveness in a rapidly shifting health care environment

SHORT TERM



## PERFORMANCE INDICATORS

# of publications

# of health economic studies completed

# of clinical trials completed

# of international presentations and abstracts

Progression of the innovation's Product-Market Fit, Business Readiness, Regulatory Compliance, and Product Development

LONG TERM



## ALBERTA IMPACTS

### Economic and Ecosystem

Health innovation ecosystem development and economic growth

### Health System Economic Value

Improve efficiency, effectiveness, accessibility, and safety



## PROGRAM PERFORMANCE INDICATORS

# of partnerships formed

# of companies that advance along the Health Innovation Cycle

# of SMEs with improved understanding of health system market access

# of regulatory approved innovations

SME investment, jobs and revenue growth

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

## How Funding Works

### (a) Project Funding

Alberta Innovates' Investment for successful Projects will be 50% of the total eligible Projects 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, the Testing Site, and/or another grant funding program. However, the SME must contribute at least 25% 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 or Testing Site 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 Investment Agreement and directly related to the Project. These costs would have to be paid for if they were not provided by either party.

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*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.*

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### (c) Eligible and ineligible expenses

Alberta Innovates only funds reasonable costs incurred. Any costs incurred prior to the Effective Date in the Investment Agreement, or costs greater than market prices are deemed ineligible. Please refer to our standard form Investment Agreement on our website to get an in-depth understand of eligible and ineligible costs.



## HOW TO APPLY



### STEP 1 Intake Form

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

Prospective Applicants are free to contact the Program Lead with any questions or concerns prior to submitting the Intake Form via the Online Application Portal.



### STEP 2 Pre-Application Meeting

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

This meeting will ensure that all parties are aligned on desired Project objectives, deliverables and outcomes.



### STEP 3 Full Application

Full Applications will be accepted at any time, subject to available funds.

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

## EVALUATION PROCESS

During the review phase, 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, market opportunity, commercialization path, 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 the Program 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.

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

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## 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-MAP 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 and Testing Site respectively.

Once we have evaluated and approved an Application for funding, Alberta Innovates will require both the SME and Testing Site 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.

## EQUITY, DIVERSITY AND INCLUSION (EDI)

Alberta Innovates believes the Research and Innovation (R&I) ecosystem is stronger and more sustainable when it is broadly reflective of the overall diversity of our community and therefore embraces the principles of Equity, Diversity and Inclusivity.

## CONTACT INFORMATION

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