

Accelerating Innovations into CarE (AICE) – Market Access program

June 15, 2022

About Alberta Innovates

Innovation is the catalyst for sustainable jobs, economic and community strength, improved health and environmental benefits. Alberta Innovates leads and accelerates innovation from discovery to use across all sectors in all parts of the province. As Alberta's largest research and innovation agency, we are uniquely positioned to propel great ideas forward to improve the lives of Albertans today and for generations to come.

Alberta Innovates believes the research and innovation (R&I) ecosystem is stronger and more sustainable when it is broadly representative of the overall diversity of our community. We strive to ensure that all interested and qualified parties have an equitable opportunity to participate and contribute to the ecosystem and that our processes are inclusive.

The projects that our programs invest in are critical to how Alberta Innovates achieves positive impact for Albertans in alignment with the Government of Alberta's R&I priorities, as expressed in our corporate Business Plan. (See the most recent Business Plan on our <u>Publications</u> page on our website.) Accordingly, it is essential for project outcomes to align with those of the program.

The Accelerating Innovations into CareE (AICE)-Market Access Program is managed through the Health Innovation and Platforms business unit within Alberta Innovates. The Health Innovation and Platforms group works closely with health service delivery partners, innovators, researchers, and patients to:

- work collaboratively with innovators to understand and reduce barriers that will accelerate innovations into care;
- facilitate the testing and adoption of novel care models that are powered by technology with a priority on digitally enabled and data-informed technologies;
- deliver skills development opportunities and build partnerships to help grow the talent needed to drive our future health economy; and
- build, integrate, and sustain platforms and activities to support a digital health ecosystem.



Program Overview

AICE – Market Access provides support for Alberta SMEs to generate the clinical, operational, and health economic evidence to facilitate market access, adoption and scaling of health innovations.

The COVID-19 pandemic has highlighted the importance of technology and innovation in the accelerated development of life-saving vaccines, digital technologies, novel diagnostics, medical devices and therapeutics. Consequently, Alberta is unlocking the full potential of its health research and development, accelerating the pace of commercialization to ensure a sustainable and globally competitive health ecosystem with a robust innovation-driven economy and improved health outcomes.

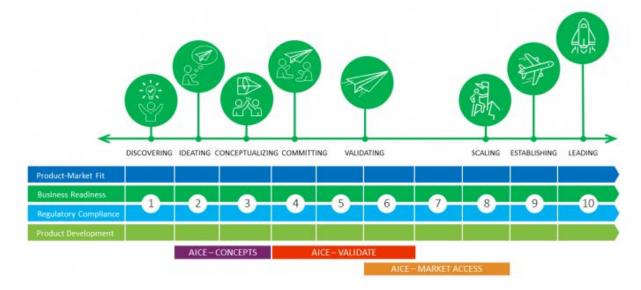
Emerging technologies, including digital and data-enabled technologies, are enabling the development of patient-focused clinical solutions, new models of care, digital therapeutics, and an acceleration of research into innovation that will form the future foundation of a more affordable, accessible, and high-quality health system for all Albertans. Alberta Innovates supports the advancement and commercialization of emerging health technology through the Accelerating Innovations into CarE (AICE) suite of programs with the goal of simultaneously delivering economic value to Alberta and health impact at home and abroad.

The AICE-Market Access program (AICE-MAP) supports Alberta's small-medium sized enterprises (SMEs) in carrying out implementation projects, feasibility studies or clinical trials of innovative health technologies in partnership with real-world testing sites ("Testing Sites") located anywhere in the world. The Program is designed to support later stage validation of health innovations that require significant clinical/user evidence before achieving market access and adoption.

The **objectives** of the AICE-Market Access program are to:

- enable market adoption and scaling of promising Alberta health innovations through generation of market-driven evidence.
- support Alberta innovators to advance their Product-Market Fit, Business Readiness, Regulatory Compliance, and Product Development of their digital health innovations during late validation and scaling phases of the client journey.

CLIENT JOURNEY AND AICE PROGRAMS



Health innovators need to consider multiple factors along their commercialization journey including Product-Market fit, Business readiness, Regulatory Compliance and Product Development. The AICE Market Access program supports innovators from stage 6-8 of this journey. Details of specific activities and milestones within each domain and stage can be found in the Detailed Health Innovation Journey Framework

The following emerging technology areas are **high priority areas** (but not a requirement) for the program:

- **Data-Enabled Innovation** technology that supports the creation, amalgamation and analysis of complex data sets to improve decision making; or
- Digital Tech for Business Transformation technology that collects, senses, measures, connects, and distributes information to improve health outcomes or realize health system economic value;

The key **outcomes** (i.e., measurable effects) the program will accomplish for the benefit of Albertans are to:

- increase the number of Alberta technologies that successfully advance along the <u>Detailed</u> Health Innovation Journey Framework , including:
 - increased # of regulatory approved technologies that enhance patient outcomes;
 - o economic diversification through increased # of health product sales; and
 - o attract investment and stimulate revenue and job growth in Alberta.

Funding

Alberta Innovates will contribute up to \$600,000 CAD (to a maximum of 50% the total eligible Project Costs) to support approved Projects over a maximum term of 24 months.

The AICE-Market Access Program provides support for up to \$600,000 over a maximum term of 24 months. A minimum of 50% of total eligible Project Costs must be provided by the Applicant as cash or in-kind contributions. Cash contributions cannot be made using funds from other Government of Alberta funding sources.

In-kind Contributions are defined as the non-cash provision of goods or services by the 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 Investment Agreement and directly related to the Project. These costs would have to be paid for if they were not provided by either party.

Alberta Innovates only funds reasonable costs incurred after an Investment Agreement is signed by Alberta Innovates and the Applicant. Any costs incurred prior to the signing of the Investment Agreement, and costs greater than market prices, are ineligible. Costs must be incurred between arm's-length entities. Please refer to the Investment Agreement sample posted on the <u>AICE-Market Access web page</u> for detailed information, including eligible and ineligible expenses.

Eligibility

Applicant Eligibility

The AICE-Market Access Program is open to:

- For-Profit Small-medium sized Organizations (SME) that are:
 - o a company with fewer than 500 full-time employees and less than \$50,000,000 annual gross revenue;
 - o incorporated in Alberta AND/OR incorporated in another jurisdiction and extra provincially registered in Alberta;
 - o a General Partnership, Limited Partnership, or Limited Liability Partnership and registered in Alberta:
 - o exist as a corporate person, with up-to-date corporate filings; and are
 - o an **Alberta-based** entity with an Albertan footprint, which is determined by a 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.

All Applicants must also:

- be authorized to undertake the proposed project, and execute a grant with Alberta Innovates on our standard terms;
- not otherwise be prohibited from receiving Alberta Innovates funding, for instance due to a past bad debt or otherwise not be in good financial standing with Alberta Innovates or its subsidiaries, InnoTech Alberta and C-FER Technologies; and

Please note: Alberta Innovates may perform corporate, bankruptcy and litigation searches, and conduct other forms of due diligence on the Applicant or Co-Applicant company and its principals.

Testing Site Co-Applicant Eligibility

All projects must include a third party independent clinical/user testing site as a Co-Applicant. Testing Sites are required to:

- Exist as a corporate person, with up-to-date corporate filings (operating anywhere in the world);
- Be authorized to undertake the proposed project;
- Demonstrate that the relationship between the Applicant and Testing Site or does not create a conflict of interest;
- Be at arm's length from the Applicant (i.e., no legal relationship with the Applicant);
- Provide a letter indicating the Testing Site's intention to participate in the Project at the time of application; and

 Not otherwise be prohibited from receiving Alberta Innovates funding, for instance due to a past bad debt or otherwise not be in good financial standing with Alberta Innovates or its subsidiaries, InnoTech Alberta and C-FER Technologies.

Project Eligibility

To qualify for funding, all Projects must:

- align with the objectives and intended outcomes of the AICE-Market Access program;
- have completed all relevant milestones up to and including Step 5 (initial Validating phase) and be focused on commercialization of health technology at Step 6-8 (in the latter Validating and Scaling stages) of the <u>Detailed Health Innovation Journey Framework</u>,
- own or have full commercial rights to 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 (<u>ITA</u>), Clinical Trial Application (<u>CTA</u>) or equivalent; or
 - not requiring regulatory approval (or an ITA/CTA or equivalent), and having a high degree of technology readiness (TRL 6 to 9) and design freeze for base technology; and,
 - possess all other necessary certification and/or privacy approvals
- focus on generating evidence against at least one testable hypothesis related to the health innovation using sound methodology that will inform key adoption influencers and payors;
- include activities across the multiple domains of Product-Market Fit, Business Readiness,
 Regulatory Compliance, and Product Development (see the <u>Detailed Health Innovation Journey Framework</u> for milestone details);
- focus on a technology that has potential to improve health outcomes (i.e., purely business management or operational clinic/hospital backend software is not a fit for this program);
- be stepped with critical "go/no go" milestones;
- be completed within the 2-year term; and
- submit to other criteria that Alberta Innovates may develop from time to time.

How to Apply?

Application intake is on an on-going continuous basis (ie. Open Call). Eligible Applicants are strongly encouraged to contact Alberta Innovates before applying. The application process involves submission of an Intake Form, followed by the Full Application. Applicants who meet basic eligibility criteria will be invited to submit a Full Application.



STEP 1 Intake Form

Complete the AICE Market Access/Validate Intake Form in our grants portal

Eligible Applicants must submit an Intake Form to establish readiness for the Program, along with relevant documents demonstrating full completion of Stage 5 of the Detailed Health Innovation Journey Framework.

Please contact Program Advisor with any questions or concerns prior to submitting the Intake Form.



STEP 2 Pre-Application Meeting

A pre-application meeting is held between the Applicant, Alberta Innovates and any relevant project partners.

This meeting ensures that all parties are aligned in terms of the program fit and desired Project objectives, deliverables and outcomes.



STEP 3 Full Application

Applicants who meet basic eligibility requirements will be invited to submit a Full Application.

Applications will be reviewed by internal and external reviewers with relevant clinical, health technology commercialization, and business investment analysis expertise.

Evaluation Process

All applications are reviewed and evaluated to determine fit with the AICE-Market Access Program objectives and intended outcomes. Alberta Innovates staff and external expert reviewers are engaged to evaluate Applications.

Alberta Innovates evaluates submitted Applications to the AICE Market Access Program based on the strength of the market opportunity, competitiveness, advance to market plan, the project plan, and potential economic impact for Alberta.

An Applicant whose Application is declined by Alberta Innovates may re-apply to the Program after a 6-month cooling-off period.

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

All investment decisions are at the sole discretion of Alberta Innovates.

Performance Measurement

Alberta Innovates invests in research and innovation activities on behalf of Albertans to help build a healthier, more sustainable and prosperous future for the province.

To maximize the impact of these investments, our funding is tied to achievement of results and outcomes. For this reason, Alberta Innovates funds on a milestone completion basis. This means the Applicant must submit a Progress or Final Report and demonstrate sufficient progress before Alberta Innovates advances the next milestone payment.

The Investment Agreement outlines the responsibilities the Applicant has in reporting Project outcomes to Alberta Innovates over the course of the Project and following completion of the Project. Outcomes of the Project may be monitored for up to five years after Project completion, so Alberta Innovates can evaluate the economic, social, health and/or environmental benefits to Alberta resulting from our investments.

Alberta Innovates has a common set of performance metrics it monitors, both at the individual Project level and for the aggregate Program. These metrics may evolve over time.

Terms and Conditions

Once we have evaluated and approved an application for funding, Alberta Innovates will require the Applicant to sign our standard-form Investment Agreement. A copy of the Investment Agreement is available on the Alberta Innovates website for your reference.

The Investment Agreement sets out in detail the roles, responsibilities and obligations of the various Parties to ensure a successful Project. Alberta Innovate 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.

Alberta Innovates will only correspond in writing and provide copies of the Application to the person named in the Application form as the one authorized to speak for the Applicant.

Should you have any questions about this guide or what is expected, please contact Alberta Innovates (see contact information below). Please note that Alberta Innovates may modify this guide from time to time in keeping with any changes to the program.

Contact Information

BINDI FERGUSON

DIRECTOR – COMMERCIALIZATION, HEALTH INNOVATION

TEL 780-306-1099

EMAIL bindi.ferguson@albertainnovates.ca