ALBERTA INNOVATES

PROGRAM GUIDE:

REAL-WORLD EVALUATION OF CANNABIS-BASED MEDICINES (mCannabis.RealWorld)

Updated 28 October 2020

ALBERTA INNOVATES OVERVIEW

Alberta Innovates is a catalyst for innovation. As a Government of Alberta corporation, Alberta Innovates supports research and innovation priorities that leads to economic growth and diversification, enhanced environmental performance, and the health and well-being of Albertans. Alberta Innovates has **three core divisions within the Research, Innovation, and Commercialization business line**, which includes **Clean Resources** (the combined legacy Clean Energy and Bio Sector), **Health Innovation**, and **Investments.** In addition, Alberta Innovates' wholly-owns **two research and development subsidiaries**, **InnoTech Alberta and C-FER Technologies** that offer a variety of contract and collaborative services.

HEALTH INNOVATION OVERVIEW

The Health Innovation team helps innovators and end-users accelerate technology development and deployment, grow their businesses, and enhance the global competitiveness of Alberta's health technology sector. We work closely with the Government of Alberta (GoA), industry stakeholders, health service delivery agents, and post-secondary institutes to understand Alberta priorities and global market trends in health research and innovation. Our programs and services emphasize a collaborative approach through partnerships with government, industry, and citizens to deliver a strong and resilient health ecosystem in Alberta by delivering programs and services across the following **four focus areas**:

People. We deliver attraction, retention, and development opportunities in alignment with the evolving health sector market needs to generate the talent needed to drive our future economy.

Health Innovation and Technology Acceleration. We work collaboratively to remove barriers that slow the innovative process. A core service offered by our team is building and operating the research services that advance the clinical and ethical requirements. We support health-technology companies

with market access by providing opportunities for development, health system partnerships, and real-world data generation.

Health System Transformation. We work closely with patients, health care delivery professionals, researchers, industry, and community partners to facilitate the development as well as the adoption of novel solutions that will transform health care delivery for patients in Alberta. This includes testing and scaling novel models of care, leveraging digital and data-enabled technology to enhance care, and empowering patients and providers to self-manage their own care when it is possible.

Emerging Health Opportunities. Health is a complex industry powered by cutting-edge innovation and driven by global trends in both healthcare and technology. We are responsive to emerging opportunities in new strategic areas; spanning the commercialization spectrum from discovery to development to market adoption.
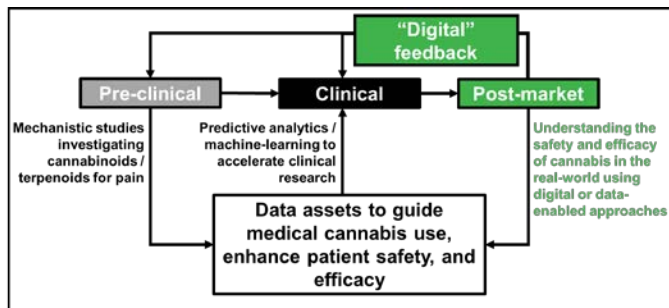
PROGRAM OVERVIEW

Background

Cannabis is the most widely consumed psychoactive substance worldwide,[1] yet its role as a therapeutic agent and its health impacts on society are poorly understood. Now more than 30% of the world, including Canada, has decriminalized or legalized cannabis.[2] Legalizing cannabis in the absence of robust clinical evidence magnifies knowledge gaps for patients, clinicians, and policymakers to make evidence-based decisions. Cannabis' complex chemistry and pharmacology is another important factor that challenges the ability to make informed decisions. Cannabis has been reported to contain more than 560 chemicals,[3-6] however very few have been extensively studied either alone or in combination. Despite limited scientific knowledge, over 329,000 Canadians are evaluating medical cannabis[7] and have self-reported to use cannabis-based products for more than 300 different medical conditions and more than 70 associated symptoms.[8] Therefore, an urgent need to close clinical or policy knowledge gaps and overcome limitations to make evidence-based decisions regarding safety and efficacy is at the forefront.

An approach to understanding the safety and efficacy of cannabis on a large scale is through post-market (i.e., after regulatory approval) studies using real-world data. Real-world data are data sources that relate to a patient or citizen's health status and / or delivery of health care routinely collected from a variety of sources,[9] typically outside of randomized clinical trials. Real-world data can provide evidence about the health outcomes of diverse patient populations in a real-world setting and provides important economics insights to inform health or policy decisions. Examples of real-world data include, but are not limited to: electronic medical records, insurance claims, billing activities, health surveys, patient registries, social media, consumer records, health apps, and mobile devices.[10]

Program Details

The Real-World Evaluation of Cannabis-Based Medicines (mCannabis.RealWorld) Program builds on the success of the Exploring Cannabis-based Medicines and Tools Program launched in 2019.

The mCannabis.RealWorld Program will fund projects that seek to address a well-defined and significant clinical or policy problem or need using real-world data.

Scheme illustrating how Alberta Innovates' is addressing evidence gaps for medical cannabis use and alignment with a typical drug development process. The original mCannabis program launched in 2019 focused on the pre-clinical setting (gray). The current program addresses the post-market or real-world setting with an emphasis on digital or data-enabled innovation (green). Thus, providing "digital" feedback to pre-clinical and clinical settings. Traditional clinical studies (phases 1 – 3) are out-of-scope for this call (black).

Alberta Innovates will contribute up to $300,000 CAD to support approved projects over a maximum term of 24 months. Successful Expression of Interest (EOI) applicants will have an opportunity to receive feedback from a unique Strengthening Panel composed of industry members, clinicians, health care research supports, and other research facilitators or data custodians to gain insights on market need or problem, available data sets, method design, and opportunities to collaborate (more details can be found below in the How to Apply, page 10 and Strengthening section, page 11). Successful EOI applicants will be eligible to receive up to $10,000 CAD to support proposal development.

Important Dates:

EOI Application Deadline	EOI Decision	Strengthening Panel	Full Proposal Application Deadline	Full Proposal Decision
October 7, 2020	Early November 2020	November 23 and 26, 2020 (*expected*)	December 16, 2020	February 2021

The Real-World Evaluation of Cannabis-Based Medicines Program supports projects that addresses a well-defined clinical or policy challenge and seeks to generate data, analyze data relationships, or curate data in a real-world setting.

How the Program Works

Eligibility

(a) Applicant Eligibility Criteria

To qualify as an Applicant, an entity must be:

- an accredited post-secondary institution, a not-for-profit corporation, or a health delivery agent;
- a legal entity with up to date corporate filings*:
  - incorporated in Alberta; or
  - a General Partnership, Limited Partnership, or Limited Liability Partnership registered in Alberta;

- demonstrate significant physical and corporate operational presence in Alberta, including appropriate Alberta ownership, and discernable intent that operational benefits will flow primarily within the province of Alberta;

- 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) Project Eligibility Criteria

To qualify for funding all projects must:

- include at least one clearly defined and significant clinical or policy problem or need that has relevance to Alberta;

- generate new data, analyze data relationships, or curate real-world data to support the problem statement;

- present a reasonable plan to provide access to the research outputs including new datasets, databases, or other data sources for broader use

- contain a digital or data-enabled component that is relevant to the real-world;

- present a reasonable plan with appropriate methods to address the problem and inform any barriers to adoption;

- include key Project milestones based on measurable goals and deliverables, stepped with critical "go / no-go" decision points;

- be completed within the 24-month term

- be able to provide a non-confidential graphical abstract; and

- submit to other criteria that Alberta Innovates may develop from time to time.

Program Objectives and Performance Measurement

The mCannabis.RealWorld Program aims to understand the safety and efficacy of cannabis at the patient or population level in a real-world setting. In addition, the Program aims to power research efforts by encouraging collaboration between Alberta academic institutions, clinicians, patients, and industry.

Over the life of a Project, Alberta Innovates employs an active Project management philosophy, regularly monitoring performance and supporting the Applicant to reach their objectives. Funding is tied to results and is informed by milestone reporting.
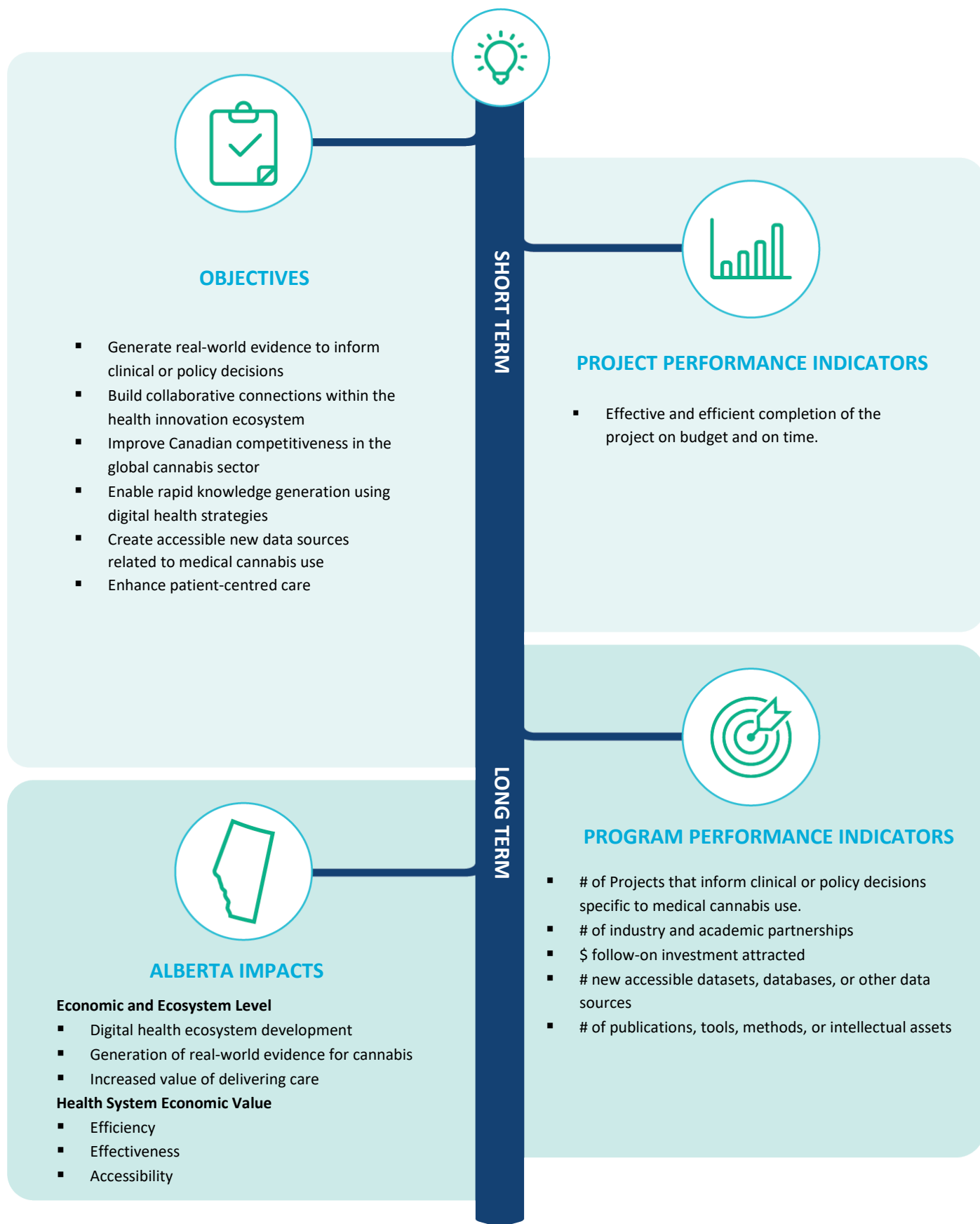
Once Projects are completed, Alberta Innovates continues to monitor performance for five (5) years to accurately evaluate the economic, social and health benefits realized for the province.

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.

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.

Objectives and Performance Metrics

OBJECTIVES

- Generate real-world evidence to inform clinical or policy decisions
- Build collaborative connections within the health innovation ecosystem
- Improve Canadian competitiveness in the global cannabis sector
- Enable rapid knowledge generation using digital health strategies
- Create accessible new data sources related to medical cannabis use
- Enhance patient-centred care

SHORT TERM

PROJECT PERFORMANCE INDICATORS

- Effective and efficient completion of the project on budget and on time.

LONG TERM

ALBERTA IMPACTS

Economic and Ecosystem Level
- Digital health ecosystem development
- Generation of real-world evidence for cannabis
- Increased value of delivering care

Health System Economic Value
- Efficiency
- Effectiveness
- Accessibility

PROGRAM PERFORMANCE INDICATORS

- # of Projects that inform clinical or policy decisions specific to medical cannabis use.
- # of industry and academic partnerships
- $ follow-on investment attracted
- # new accessible datasets, databases, or other data sources
- # of publications, tools, methods, or intellectual assets

How Funding Works

(a) Project Funding

Alberta Innovates' Investment to a successful Applicant is up to $300,000 CAD per Project for a term not to exceed 24 months. Successful EOI Applicants will be eligible for up to $10,000 CAD in full proposal development funds. The funds are provided to cover Eligible Expenses only. Industry partnerships are encouraged. Funded projects will be required to provide a graphical abstract.

Disbursement of Alberta Innovates' Investment is determined on a case by case basis depending on the risks and needs of each successful Project, but funds will only be disbursed upon approval of required Progress and Final Reports.

Alberta Innovates will contribute up to $300,000 CAD to support approved Projects over a maximum term of 24 months. Successful EOI Applicants will be eligible for up to $10,000 CAD in full proposal development funds.

(b) Eligible and Ineligible Expenses

Alberta Innovates only funds reasonable costs incurred after the Effective Date on an Investment Agreement with you. Any costs incurred prior to the Effective Date in the Investment Agreement, or costs greater than market prices are deemed ineligible. Costs must be incurred between arm's length entities. Please refer to our standard form Investment Agreement found on our website to get an in-depth understanding of eligible and ineligible costs.

HOW TO APPLY

STEP 1
Expression of Interest Application (Stage 1)

Deadline: October 7th, 2020 at 4:00 PM MST

Adjudication: EOIs will be reviewed by November 4th, 2020. Successful applicants will be notified and be invited to proceed to Stage 2 (Full Proposal) and be invited to present to a proposal strengthening panel.

Applicants are strongly encouraged to check Alberta Innovates Program website to access available data resources (supplied by volunteer panel members).

Successful EOI applicants: Eligible for up to $10,000 to support full proposal development.

STEP 2
Strengthening Panel

Strengthening Panel dates: 23 and 26 November 2020 (*Expected*)

Intent:
1) To provide feedback to applicants on problem, method design, data sources, and relevance.
2) Explore opportunities to collaborate.
3) Not to adjudicate.

Format:
Virtual and closed meeting
15 min oral presentation
30 min panel feedback

Successful EOI applicants: At least one member of the team must present at a strengthening panel meeting.

STEP 3
Full Proposal (Stage 2)

Deadline: December 16th, 2020 at 4:00 PM MST

Adjudication: Detailed full proposals will be reviewed by a panel of external experts by early February 2021. Full proposals must have consistent scope with approved EOI; otherwise may be excluded from competition. Funding announcements and agreements expected by March 31, 2021.

Questions: Applicants are encouraged to discuss with senior business partner (contact details below on page 12).

STRENGTHENING PANEL

The composition of the strengthening panel is a mix of industry, clinicians, academics, and health-care delivery agents (logo representations below). The role of the unique strengthening panel is to provide feedback on the proposal and identify opportunities to collaborate. The strengthening panel is not an adjudication process. The format of this virtual session would be a 15-minute oral presentation followed by a 30-minute two-way conversation. Successful Stage 1 Applicants will be provided an outline to help structure their presentation.

Current members

EVALUATION PROCESS

Alberta Innovates leverages internal staff and external expert reviewers to evaluate the Applications submitted. Alberta Innovates evaluates promising projects based on criteria related to the **opportunity**, **impact potential**, **project design**, and **innovative use of real-world data**. Detailed evaluation criteria are outlined in the online Application form.

Alberta Innovates retains 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.

The assessment criteria 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 a 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 person named in the Application form as the one authorized to speak for the Applicant.

Once we have evaluated and approved an Application for funding, Alberta Innovates will require the 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)

Alberta Innovates believes the Research and Innovation 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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Version 2 – This version supersedes previous versions.

References

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