



ALBERTA
CLINICAL RESEARCH CONSORTIUM

MANAGED BY ALBERTA INNOVATES

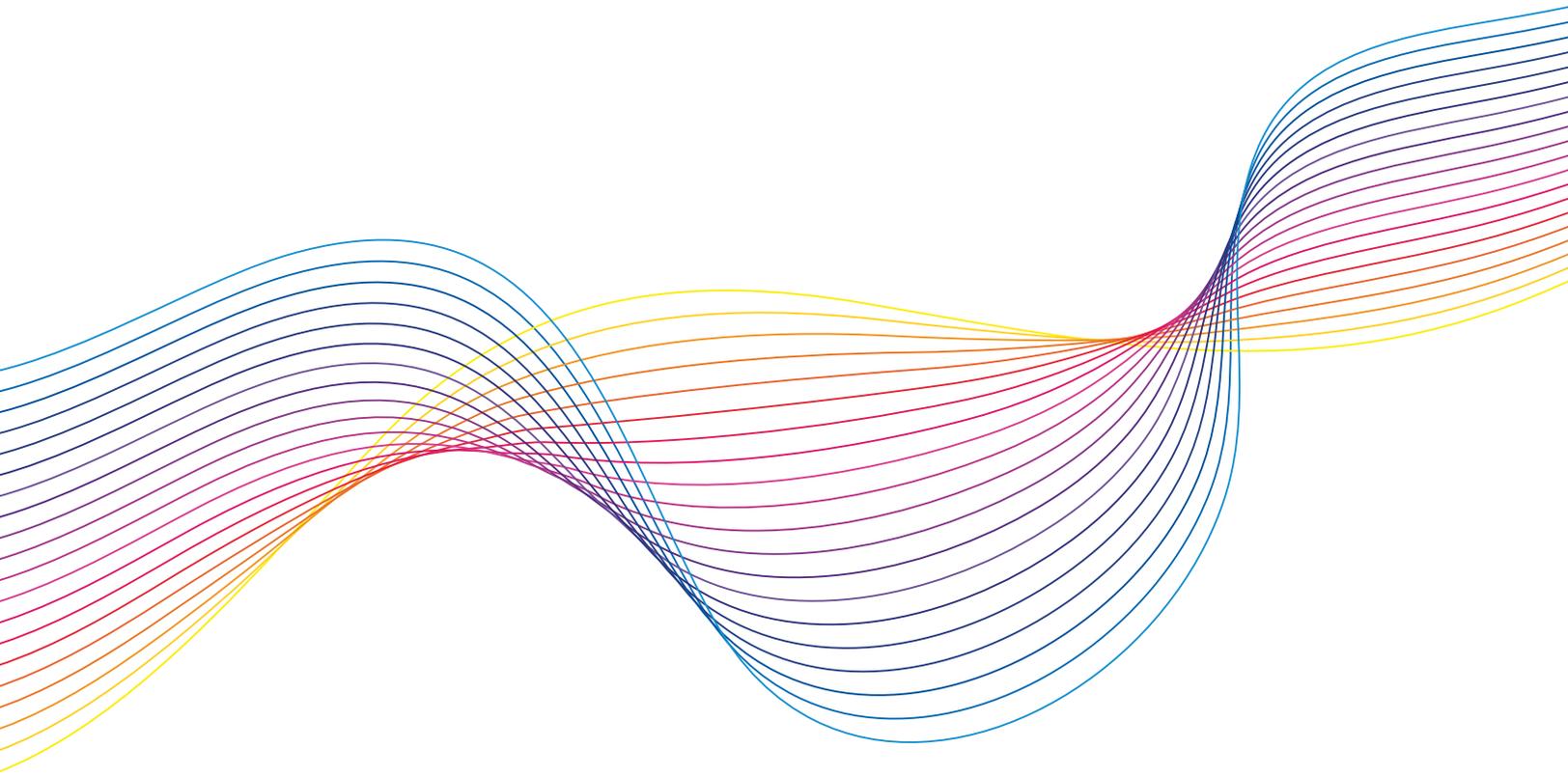
ALBERTA CLINICAL RESEARCH CONSORTIUM

Strategic Plan Phase II

2018-2020

“Our vision is high quality, integrated, and efficient clinical health research in Alberta”

ALBERTA CLINICAL RESEARCH CONSORTIUM



The Alberta Clinical Research Consortium consists of Alberta Health Services, Alberta Innovates, Alberta SPOR SUPPORT Unit, College of Physicians & Surgeons of Alberta, Covenant Health, University of Alberta, and University of Calgary. The Consortium works closely with many of Alberta’s research groups including Calgary Centre for Clinical Research and Northern Alberta Clinical Trials + Research Centre.

As a proud partner of the ACRC, Alberta Innovates is pleased to provide project management and secretariat support for the initiative.



STRATEGIC PLAN PHASE II

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ABOUT THE ALBERTA CLINICAL RESEARCH CONSORTIUM

The Alberta Clinical Research Consortium (ACRC) began when leaders from the research community identified the need to increase alignment and coordination of administrative processes for clinical health research in Alberta. The ACRC involves academic, health care systems and community-based researchers, study coordinators, and administrators from across Alberta with a shared recognition that research processes need to be streamlined to achieve a positive climate for clinical health research in Alberta. The Executive Committee of the ACRC was established in March 2011 to provide ongoing strategic leadership in the development of an integrated approach to clinical research. Members of the Executive Committee are senior clinical research representatives endorsed by their respective institutions: Alberta Health Services; Alberta Innovates; Alberta SPOR SUPPORT Unit; College of Physicians & Surgeons of Alberta; Covenant Health; University of Alberta; and University of Calgary.

ACRC Partners



EXECUTIVE SUMMARY

The Alberta research community is working together to be competitive and attract outstanding clinical researchers and clinical research investment to the province. Since the inception of the Alberta Clinical Research Consortium (ACRC) in 2011, Alberta has aligned around a common definition of clinical health research (*def. p.6*) and continues to build upon its vibrant clinical research foundation. Through coordination and alignment, the province is improving access to clinical health research benefitting the health and socio-economic well-being of Albertans.

In 2011, researchers and representatives from universities, health care systems, and communities across Alberta discussed how to improve clinical research in the province. At this inaugural meeting, participants described their vision for a better clinical research environment and outlined the strategic plan to achieve this vision. In Phase I, the ACRC undertook activities that have helped to catalyze and promote efficient, integrated, high quality clinical research in Alberta in three strategic areas including efficiency of research administration, standardization of clinical research legal reviews, contracts and agreements, and training. In addition, four enabling actions were developed to support the initiative: common terminology used across the province; communication strategy that effectively engages and informs individuals; information management structure that facilitates seamless exchange of information; and, evaluation strategy that monitors implementation and assesses the impact of the initiative on clinical research.

Key Phase I accomplishments include:

- The Glossary and Common Terminology
- The Clinical Research Source
- Agreed upon provincial metrics
- Research management system used in several areas
- Tools, templates and guidance documents
- Alberta Clinical Research Roadmap
- Provincial training opportunities

Optimizing Clinical Health Research in Alberta

Stakeholder meetings, advisory group interviews and the baseline survey have guided the Phase II plan.

The ACRC is entering Phase II with new strategic priorities:

1. Improve the efficiency of clinical health research administrative processes across the province.
2. Engage industry, funders, senior leaders, the public and community physicians to increase opportunities for Alberta clinical health researchers and patients.
3. Identify the enabling actions, assets, resources and infrastructure for sustainable, integrated clinical health research.

Following approval of the strategic plan by the ACRC Executive Committee, working groups will be established for each strategic priority. Each working group recommends the actions, performance metrics, and timelines to achieve success for its respective strategic priority to the ACRC Executive committee.



Alberta's Assets

Alberta has many assets that support an aligned clinical health research process some of which include:

1. A unified health care delivery system under one provincial administration of Alberta Health Services with strategic partners (Covenant Health), that facilitates access to patients and services needed for clinical health research.
2. A strategically aligned and integrated health research and innovation system supported by Alberta Innovates.
3. Two strong medical schools geographically located in the North (University of Alberta) and the South (University of Calgary).
4. An action-oriented approach already addressing the alignments needed to facilitate and support clinical health research. Some recent activities include:
 - › Alberta Health Research Ethics Harmonization (HREH) Initiative to develop streamlined ethics review process among the three research ethics boards designated in the Health Information Act.
 - › The Alberta SPOR SUPPORT Unit (AbSPORU) is a virtual network of services that provides support for patients and researchers to increase the quantity and quality of patient-oriented research.
 - › Secondary Use Data Project (SUDP) aiming to use Alberta's health and health-related data more effectively.
 - › University of Calgary's Clinical, Health Sciences, and Population Health Research Platform Strategy and expanded infrastructure to support clinical health research.
 - › NACTRC-led launch of the Bethecure.ca campaign increasing awareness of health research and actively recruiting clinical trials in collaboration with Alberta Health Services and the Universities of Alberta and Calgary.
 - › Alberta Health Services position as number 16 in Canada's top research hospitals/health authorities in 2016 and expanded research supports.
 - › Covenant Health's focus on vulnerable populations, development of multi-disciplinary teams, and support of new researchers.

INTRODUCTION

The name of the initiative, Alberta Clinical Research Consortium (ACRC), reflects the collaborative and synergistic efforts of clinical researchers and administrators from academic institutions, health care systems, and the community. Specifically, the term “consortium” was selected to signify that the initiative is “an association or grouping of institutions or organizations, usually set up for a common purpose that would be beyond the capabilities of a single member of the group.”¹

In the five years since the inception of the ACRC, Alberta has made significant advances in clinical research areas that have not only changed the practice of medicine, but also the understanding of diseases and its impact on patients and families. These advances have not been made in silos but through the combined knowledge and activities of our partner organizations and initiatives. The ACRC leverages and builds on excellence in research and other activities across the province.

This plan documents new and ongoing opportunities identified by researchers and representatives of Alberta’s major institutions involved in clinical health research. The Optimizing Clinical Health Research meeting held on December 5, 2016 in Edmonton, was a key opportunity for stakeholders to provide input. Attendees representing diverse research backgrounds and regions across Alberta, explored ways to enhance the climate for clinical research in Alberta.² The day-long program incorporated both small and large group discussions and activities to set priorities, identify outcomes, and propose actions to optimize clinical health research in Alberta over the next two years. This strategic plan outlines priorities relevant to the vision of the ACRC as identified by this group of stakeholders, and presents action plans, key steps and proposed projects in order to achieve the desired goals.

This Strategic Plan will align with government direction set out through the Alberta Innovation Research Framework (ARIF). Our strategy aims to improve access to clinical research, assist with better utilization of resources, and ensure a vibrant clinical research environment. This will help bring the latest diagnostic tools, prevention methods, and treatments to Albertans.

The Alberta Definition of Clinical Health Research

Definition aligned with ACRC partner organizations.

Clinical Health Research

(Alberta-specific terminology)

Clinical (health) research has the goal of improving the diagnosis, prevention and treatment (including rehabilitation and palliation) of disease and injury, and improving and evaluating the health and quality of life of individuals. Clinical research is conducted on, or for the treatment of human participants. Clinical research includes living human participants, human tissues, human remains, cadavers, biological fluids, embryos, fetuses and patient information. This includes clinical trials on patients, epidemiological and behavioral studies, outcomes research, health services research and population health studies, typically falling under the CIHR rubric of pillars 2, 3 & 4.

– **ACRC Glossary and Common Terminology (2017)** Version 2.2. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual.

¹ Encarta® World English Dictionary [North American Edition] ©2009

² Optimizing Clinical Research Day, December 5th, 2016, Meeting Proceeding. ACRC (2017)

PHASE I IN SUMMARY

In 2013 the ACRC's Inaugural Strategic Plan was released. The plan focused on three strategic priorities to effectively pursue the ACRC vision of "high quality, integrated, and efficient clinical health research in Alberta." The intent of these priorities was to improve the leveraging of assets in Alberta's current clinical research environment. Key impacts from ACRC Phase I activities are diagrammed on the next page.

The three initial strategic priorities centered on three outcomes are:

1. Make Clinical Health Research in Alberta, Clear, Simple, Transparent and Efficient
2. Promote Consistency in Legal Review Related to Clinical Research
3. Develop High Quality and Specialty Clinical Research Investigators and Staff

Four enabling actions were undertaken to support the inaugural strategic priorities:

1. Common terminology used across the province (i.e. Glossary & Common Terminology, Version 3.0).
2. Communication strategy that effectively engages and informs a broad range of stakeholders about the ACRC initiative and clinical research activities across the province (i.e. Clinical Research Source).
3. Information management structure that facilitates seamless exchange of appropriate information across institutional sites and enables provincial reporting.
4. Evaluation strategy that uses performance metrics to monitor implementation of strategies and assess the impact of the initiative on clinical research.

Broadly, the ACRC aims to impact the clinical research landscape in 4 key areas:



PEOPLE

Professional development and networking opportunities that enhance quality research.

TOOLS

Provincially standardized, best practice tools, templates and guidance documents, rooted in quality by design.

PROCESSES & TECHNOLOGY

Streamlined, and coordinated processes and IT systems for conducting clinical research from study start to close.

CULTURE

Integration of research into clinical care. The public, researchers and health care systems all value and invest in clinical health research.

**High Quality, Integrated
Clinical Health Research**

ACRC PHASE I KEY IMPACTS

The ACRC has made key impacts in several areas including clinical research administration, institutional policy, legal, as well as tools and resources for clinical researchers and staff. These impacts collectively aim to improve the efficiency, integration and quality of clinical health research across health care systems, academic institutions and the community in Alberta.

ACRC Phase I Key Impacts



COLLABORATION & CO-DEVELOPMENT WITH ACRC PARTNERS



ENGAGEMENT AND EVALUATION TO INFORM PHASE II STRATEGY

ACRC has an evaluation strategy that uses performance metrics, key informant interviews and other qualitative approaches to monitor and assess the impact of the initiative.



Evaluation of key stakeholder interviews, surveys and informal opinion gatherings have resulted in real world examples for the ACRC to provide meaning and utility for the clinical health research community. These evaluations have been used internally and shared with ACRC Executive Committee members to provide valuable guidance to develop ACRC strategy and enable continuous improvement for the consortium. Working with the input of Performance Management and Evaluation at Alberta Innovates, the ACRC approach is outlined in the ACRC Inaugural Strategic Plan (2012) and the ACRC Logic Model.

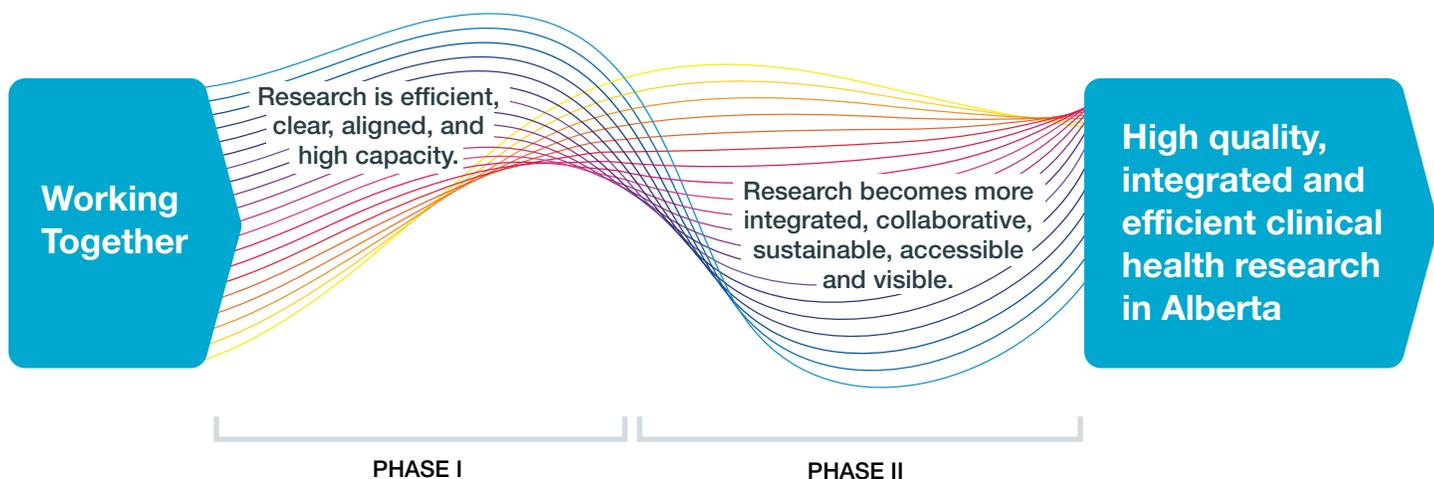
Key stakeholder engagement and supporting documents generated have included:

ACRC Baseline Survey (2014): An online survey disseminated in 2013 to capture an understanding of researchers, study staff and administrator experiences and satisfaction with clinical health research in Alberta.

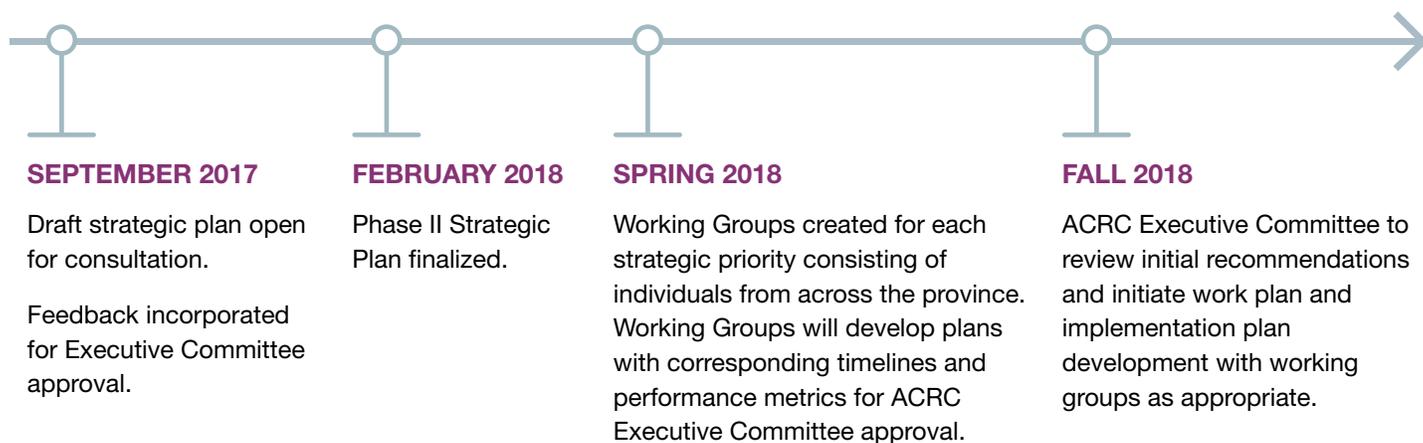
ACRC Clinical Research Conference Attendee Survey (2013, 2015): An attendee satisfaction survey to capture feedback on the utility, effectiveness and appreciation for an educational & networking conference designed for operations-level clinical researchers and administrators.

Optimizing Clinical Health Research (2016): Researchers and representatives of Alberta's major institutions involved in clinical research held a meeting on December 5, 2016 in Edmonton to explore ways to enhance the climate for clinical research in Alberta. Throughout the day's activities, this representative group identified the key barriers and opportunities for all local, institutional and provincial initiatives aimed at improving and enhancing clinical health research in Alberta.

ACRC's Path to Clinical Health Research Success



Next Steps and Timeline

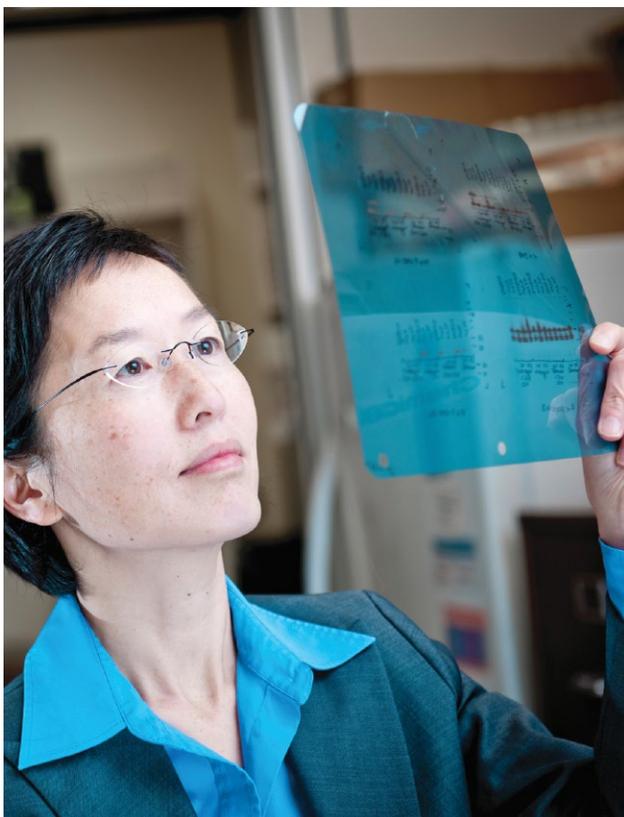


- Alberta Innovates provides project management and coordination for activities of the initiative.
- Updates on the initiative will be available on the Alberta Innovates website, or via newsletters, ACRC advisory group updates and other mechanisms.

PHASE II ACRC STRATEGIC PRIORITIES (2018–2020)

THE PLAN IN SUMMARY

High Quality, Integrated and Efficient Clinical Health Research in Alberta



Five ACRC Enabling Actions will be undertaken to support the above Strategic Priorities:

1. Common terminology used across the province.
2. Communication strategy that effectively engages and informs individuals.
3. Information management structure that facilitates seamless exchange and linkage of appropriate information across institutional sites.
4. Provincial guidelines for clinical health research training.
5. Evaluation strategy that uses performance metrics to monitor implementation of the priorities and to assess the impact of the initiative on clinical health research.

Strategic Priority 1

Make Clinical Health Research in Alberta Clear, Simple, Transparent, and Efficient

STRATEGY

Improve the efficiency of clinical health research administrative processes across the province

BACKGROUND

There are multiple steps and approvals required throughout a clinical trial—from the initial concept and design, through recruitment, data collection, to the end of the study. Each institution has site specific processes which can be challenging in multicentre studies where researchers must obtain approvals from each site. Promotion of integration, standardization and best practice across the province can help to address these challenges. ACRC recognizes the importance of efficient, coordinated and integrated processes across clinical health research administration departments to benefit participants and the research community.

ACTIONS, PLANS AND KEY STEPS

1. Using the existing Alberta Clinical Research Roadmap as a basis, provide tools that assist researchers to navigate the “concept to close” pathway in Alberta. The tools, templates, regulations, services, best practice and other relevant materials will be developed with all ACRC partners.
2. Develop guidelines, best practice recommendations, training guides and common tools or templates to assist investigators with paperless study management.
3. Develop case studies for effective multi-site clinical health research project set-up. Create a reference document with exemplars of multi-site studies coordinated from and within Alberta.
4. Mobilize knowledge of study results in plain language with research participants that helps promote research findings into standard of care.
5. Develop clear, concise provincial indicators that showcase Alberta’s strengths and abilities.

PROPOSED PROJECTS

- Alberta Clinical Research Roadmap: Provincial services index to assist clinical researchers with navigation from concept to close of a study
- Paperless management: Study e-regulatory binder template, digital data management guidance, e-Informed Consent guidance documents
- Case study outlining a multi-site study in Alberta
- Platform offering study findings with plain language to public

Strategic Priority 2

Partnerships and Participation in Clinical Health Research

STRATEGY

Engage industry, funders, senior leaders, the public and community physicians to increase opportunities for Alberta clinical health researchers and patients

BACKGROUND

Alberta has built capacity in clinical health research. New opportunities exist to build relationships with pharmaceutical and industry partners, enable Albertans to find out about and participate in clinical health research, and increase opportunities for clinical health research in community settings.

ACTIONS, PLANS AND KEY STEPS

1. Identify the opportunities and challenges for industry (sponsors) of clinical health research in Alberta.
2. Build awareness of clinical health research and available tools and services for Alberta researchers including community physicians.
3. Create opportunities for the ACRC and related provincial initiatives to showcase clinical health research in Alberta.
4. Develop tools and guidance documents for community physicians in clinical health research.

PROPOSED PROJECTS

- Leverage planned activities to showcase, market and promote clinical health research in Alberta
- Showcase the Alberta research community through a dashboard of provincial clinical health research indicators and a community clinical health research day
- Guidance, webinars and support documents related to permission-to-contact, records management and clinical health research in the community
- Clinical health research review with industry, funders, government and academic stakeholders

Strategic Priority 3

Sustainable, Integrated Clinical Health Research

STRATEGY

Identify the enabling actions, assets, resources and infrastructure for sustainable, integrated clinical health research

BACKGROUND

Currently, the constraints in Alberta to participating in clinical health research and the phenomenology behind a “one and done” approach to conducting clinical health research studies are not well understood. The ACRC will identify the infrastructure, support and environmental needs to support clinical staff and researchers to move from a “one and done” situation into a sustainable clinical research career as well as the right conditions for an integrated clinical health research program in clinical departments.

ACTIONS, PLANS AND KEY STEPS

1. Environmental scan of assets, resources, and infrastructure of clinical departments enabled to support clinical health research.
2. Gather feedback from researchers and clinical departments on the enabling actions to sustaining a clinical health research program.
3. Create a white paper containing enablers and recommendations for an integrated research/healthcare model.

PROPOSED PROJECTS

- Key informant interviews and inventory-taking with:
 - › Clinical researchers with extensive experience and those who have conducted trials or studies in the past but who have not continued
 - › Clinicians looking to participate more actively in clinical health research
 - › Clinical department heads and staff
- Complete an environmental scan of successful integrated research models from other jurisdictions
- Report on key elements identified that enable clinical health research integration into clinical environments

ACRC ENABLING ACTIONS

In Phase II, five enabling actions will be maintained in support of the strategic priorities:

1. Common terminology used across the province.

Speaking the same language is important in developing clear, province-wide processes. The ACRC will work with various organizations in continuing to develop common terminology to avoid ambiguity.

2. Communication strategy that effectively engages and informs individuals.

Keeping everyone informed and updated is crucial. The ACRC will continue to develop and implement an active, two-way communication strategy to reach a broad range of stakeholders. Activities will include:

- a. Alberta Clinical Health Research Conference or similar training event
- b. Clinical Research Source Newsletter or relevant communications and briefs
- c. Alberta Clinical Research Roadmap and online asset lists

3. Information management structure that facilitates seamless exchange and linkage of appropriate information across institutional sites.

Different administrative processes often require the same or similar information be presented in a variety of formats. To improve efficiency and avoid duplication of work, the Consortium will assess what information may be collected and for what purpose, and facilitate this exchange of information as appropriate.

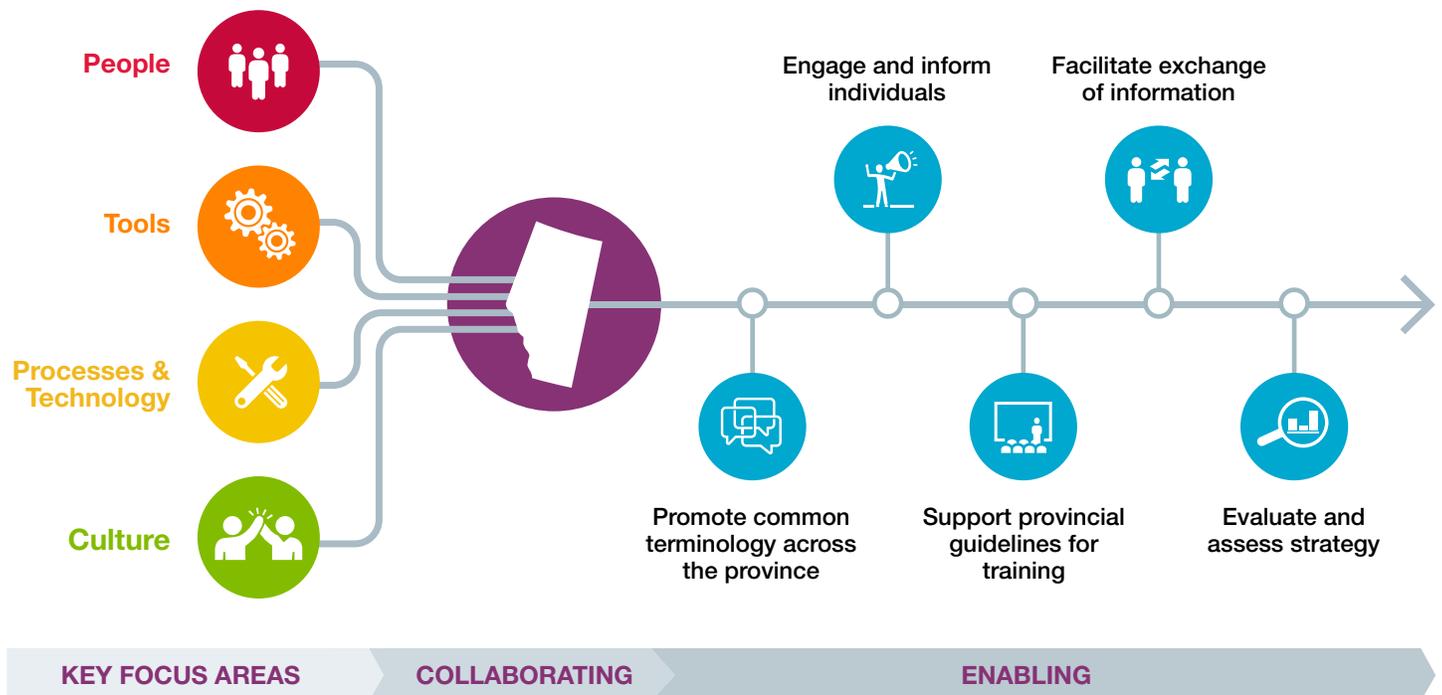
4. Provincial guidelines for clinical health research training.

The ACRC will continue to endorse standardized and appropriate training for clinical health researchers and staff in Alberta.

5. Evaluation strategy that uses performance metrics to monitor implementation of the priorities and to assess the impact of the initiative on clinical health research.

These metrics will continue to help support decision-making and reporting. The initiative and its strategic priorities will continue to be evaluated and assessed individually, and as a whole.

ACRC: Catalyzing Change in Clinical Health Research



APPENDIX A: STAKEHOLDERS

ACRC strives to work collaboratively and to align with similar local, national and international initiatives. Below is a list of entities in the various stakeholder groups that are involved in or with the ACRC initiative:

INITIATIVES

Alberta SPOR SUPPORT Unit (AbSPORU)
Health Research Ethics Harmonization (HREH) Initiative
Secondary Use Data Project (SUDP)

FUNDERS

Alberta Innovates (AI)
Canadian Institutes of Health Research (CIHR)
National Sciences and Engineering Research
Canadian Agency for Drugs and Technologies in Health

GOVERNMENT

FEDERAL

Health Canada
Foreign Affairs & International Trade Canada

PROVINCIAL

Ministry of Economic Development and Trade
Alberta Health

MUNICIPAL

Cities in Alberta

PRIMARY CARE NETWORKS

Strategic Clinical Networks
Health Professional Organizations
Alberta College of Physicians & Surgeons
Alberta College of Pharmacists
College & Association of Registered Nurses of Alberta
Health Sciences Association of Alberta

HOSPITALS

Alberta Health Services (AHS)
Covenant Health

PATIENTS AND PUBLIC

ENTERPRISE DEVELOPMENT

Innovate Calgary
TEC Edmonton

PHILANTHROPIC ORGANIZATIONS

Provincial, National, and International
Alberta Cancer Foundation

POST-SECONDARY INSTITUTIONS

University of Alberta
University of Calgary
University of Lethbridge

RESEARCH ETHICS BOARDS

Health Research Ethics Board (HREB)
University of Alberta
Conjoint Health Research Ethics Board (CHREB),
University of Calgary
Health Research Ethics Board of Alberta (HREBA),
Alberta Innovates

RESEARCH NETWORKS/ALLIANCES

Provincial, National, and International

RESEARCH ADMINISTRATIVE UNITS

Alberta Cancer Clinical Research Trials (ACCT)
Calgary Centre for Clinical Research (CCCR)
Covenant Health Research Centre (CHRC)
Northern Alberta Clinical Trials and Research Centre (NACTRC)

RESEARCHERS AND RESEARCH STAFF

INDUSTRY

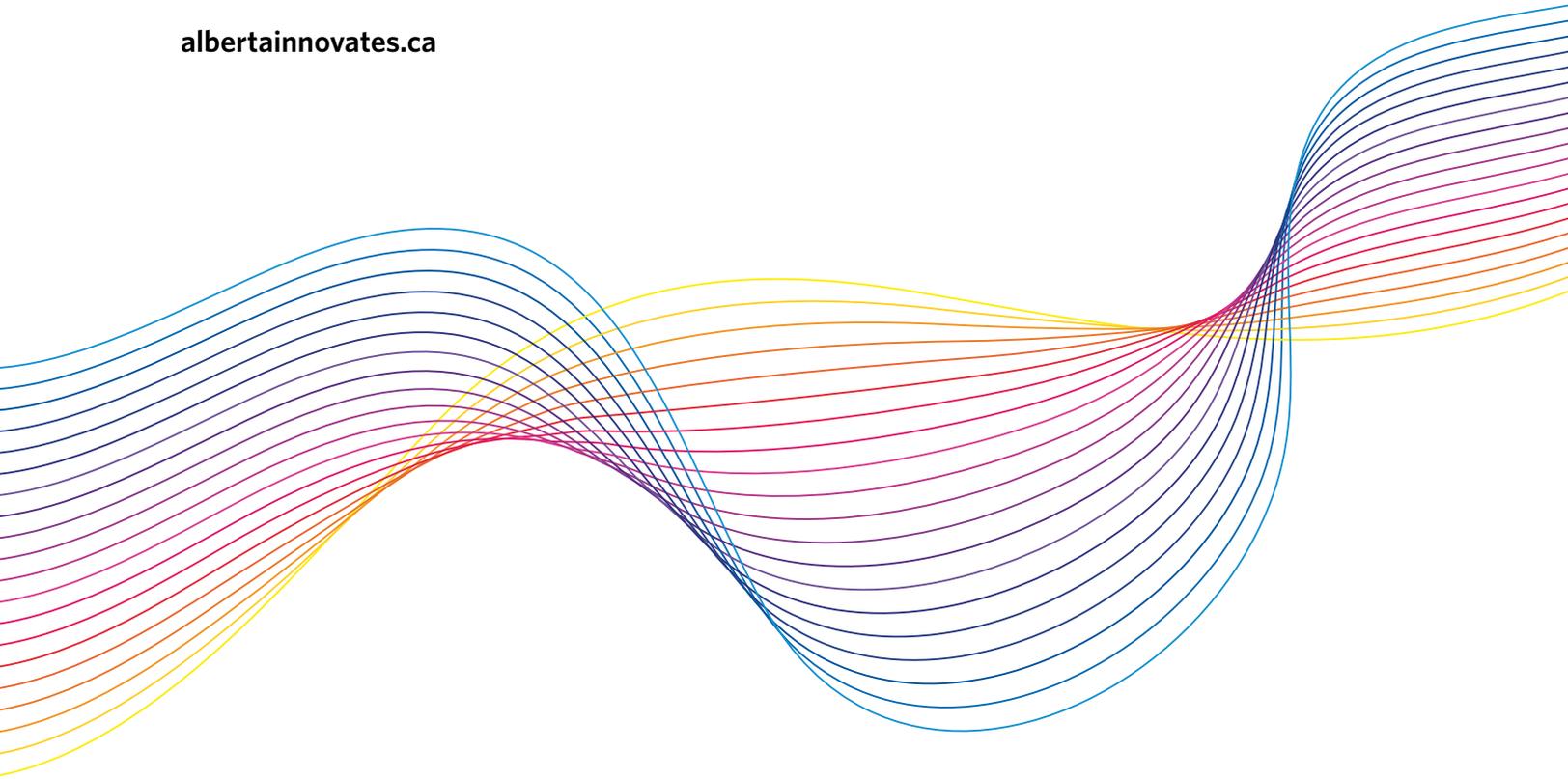
Cooperative Groups/Biotech Companies

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