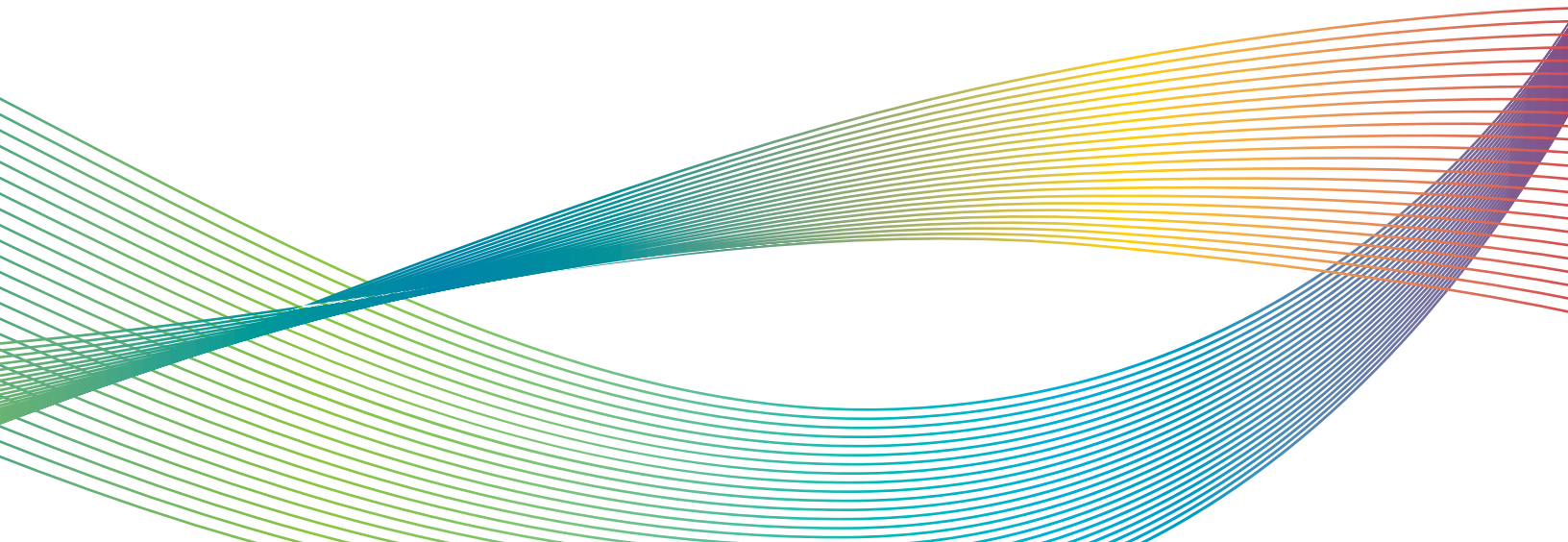
ALBERTA CLINICAL RESEARCH CONSORTIUM

ACRC
Inaugural Strategic Plan

March 2012



"Our vision is high quality, integrated, and efficient clinical research for Alberta"

ALBERTA CLINICAL RESEARCH CONSORTIUM MAY 30, 2011

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Table of Contents

Executive Summary

In the global context, Alberta needs to enhance its ability to be competitive in attracting outstanding clinical researchers and clinical research investment to the province while simultaneously aligning itself with the various national strategies. With renowned researchers and research centres of excellence, Alberta has a vibrant clinical research foundation to build on. These elements of success can be strengthened through better coordination and alignment of processes to improve access to clinical research, benefiting the health and socio-economic well-being of Albertans.

On May 30, 2011, researchers and representatives from universities, healthcare 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.

Three strategic priorities were identified for the first phase of the Alberta Clinical Research Consortium (ACRC):

1. Improve the efficiency of clinical research administrative processes across the province.
2. Standardize legal review guidelines of contracts and agreements related to clinical research.
3. Develop provincial standards and opportunities for clinical research training.

Four enabling actions will be undertaken to support the initiative:

1. Common terminology used across the province.
2. Communication strategy that effectively engages and informs individuals.
3. Information management structure that facilitates seamless exchange of information.
4. Evaluation strategy that monitors implementation and assesses the impact of the initiative on clinical research.

Following approval of the strategic plan by the ACRC Executive Committee, working groups have been established for each strategic priority. Each working group has recommended the actions, performance metrics, and timelines for its respective strategic priority to the Executive Committee. Alberta Innovates - Health Solutions (AIHS) is facilitating and providing secretariat support and project management for the initiative.

Introduction

This report documents agreements reached by researchers and representatives of Alberta's major institutions involved in clinical research at a meeting held on May 30, 2011 in Edmonton. The attendees, representing diverse research backgrounds and regions across Alberta, explored ways to enhance the climate for clinical research in Alberta.[1]

The name of the initiative, Alberta Clinical Research Consortium (ACRC), reflects the collaborative and synergistic efforts of clinical researchers and administrators from academic institutions, the healthcare system, and the community. Specifically, the term "consortium" was selected to signify that the initiative is "an association or grouping of institutions, businesses, or financial organizations, usually set up for a common purpose that would be beyond the capabilities of a single member of the group."[2]

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. The ACRC leverages and builds on excellent research, as well as other related activities across the province, and aligns its efforts with those being put forth on the national stage. The ACRC strategies aim 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.

About the *ACRC*

The ACRC began in 2010 when leaders from the clinical research community identified the need to increase alignment and coordination of administrative processes for clinical research in Alberta.

The ACRC involves both academic and community-based clinical research leaders, study coordinators, and administrators from across Alberta with a shared recognition that research processes need to be streamlined in order to achieve a positive climate for clinical 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 who are endorsed by their respective institutions: Alberta Health Services; College of Physicians & Surgeons of Alberta; Covenant Health; University of Alberta; University of Calgary; and Alberta Innovates – Health Solutions.

[1] For a list of meeting attendees, please see Appendix A.
[2] Encarta® World English Dictionary [North American Edition] ©2009

The Plan in Summary

To effectively pursue the ACRC vision of "high quality, integrated, and efficient clinical research in Alberta," the meeting participants identified three initial top strategic priorities for the ACRC. The intent of the strategic priorities is to improve the leveraging of assets in Alberta's current clinical research environment. These priorities, diagrammed below, are inter-related (and sometimes interconnected), and are essential to achieving the central, shared vision.

High Quality, Integrated and Efficient Clinical Research in Alberta

Four 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 a broad range of stakeholders about the ACRC initiative and clinical research activities across the province.
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.

A Working Group for each strategic priority has detailed a list of actions, performance measures, and timelines for the ACRC Executive Committee.

The ACRC is working with the Alberta Health Research Ethics Harmonization Initiative to achieve efficiencies for research in the province.

Key ACRC Stakeholders

The ACRC initiative will impact a number of people involved in clinical research across the province. This includes clinical researchers and staff, research units, and the institutions. Invitees to the strategic planning form the ACRC Advisory Committee, who will be requested to provide input on the initiative.

Other key stakeholders include the public; the province's health organizations; industry and cooperative groups involved in clinical research in the province, nationally, and internationally; provincial health professional associations; the corporations of Alberta Innovates (AI); Alberta Ministries of Advanced Education and Technology and Health and Wellness; a number of federal ministries including Health Canada and Industry Canada; research funders, networks, and alliances at the provincial, inter-provincial, and national levels; patient support groups; and a range of philanthropic organizations that fund health research. The ACRC also strives to work collaboratively and align with a number of similar national and international initiatives. See Appendix B for an initial listing of entities in the various stakeholder groups outlined above.

Alberta's Assets

Assets that support an aligned clinical research process in Alberta include:

- A culture of excellence in collaborative clinical research across disciplines and clinical research units in metropolitan and rural settings.
- Alberta's clinical researchers have contributed to and received international recognition in many areas including:
  - Child and maternal health – pediatric thrombosis, cardiology, neurology, and stroke research;
  - Cancer – breast, gastrointestinal, neuro-oncology, prostate, imaging, melanoma, and phase I clinical trials; and the development of the cancer corridor in Lethbridge, Red Deer, and Grande Prairie;
  - Chronic diseases – cardiology, genitourinary, rheumatology, and rehabilitation medicine.
- An integrated health care system led by Alberta Health Services working with strategic partners, such as Covenant Health, to facilitate access to patients and services needed for clinical research.
- Alberta Innovates – Health Solutions and other Alberta Innovates corporations support a strategically aligned and integrated health research and innovation system.
- An action-oriented approach already addressing the alignments needed to facilitate and support clinical research. Activities include:
  - The Alberta Health Research Ethics Harmonization Initiative of the six Health Information Act-designated Research Ethics Boards (REBs) in the province;
  - Netcare – a single, province-wide Electronic Health Record (EHR) that provides key patient health information at the point of care;
  - Province-wide pricing for diagnostic imaging, medical records, and laboratory, pharmacy and cardiology services.

Strategic Priority 1

Making Clinical Research in Alberta Clear, Simple, Transparent, and Efficient

STRATEGY Improve the efficiency of clinical 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 its own processes which is especially challenging in multi-centre studies where researchers have to obtain approvals from each site. A unified, province-wide approach would improve this process by eliminating unnecessary steps, while applying a risk-based approach to value-added steps.

Actions Plans and Key Steps:

1. **One clear and transparent clinical research administrative roadmap for the province**
   - Using the existing processes as a basis and applying lean principles, which focuses on eliminating duplicative and unnecessary work, define the ideal roadmap. The roadmap will incorporate appropriate oversight, applicable regulations, risk mitigation, patient safety and data integrity, initial and ongoing institutional approvals, and local sub-processes by type of study.
2. **Coordinated approach for research reviews**
   - Develop a coordinated, efficient, streamlined process (flow of communication, information, delegated reviews) of common review processes and identify sub-processes for department or unit-specific reviews.
3. **Study budgeting tools and templates**
   - Develop common templates to assist investigators with study budgeting.
4. **Guidance document for archiving clinical research records**
   - Create a common guidance document on archiving with local sub-processes.

Initial Milestones and Projected Development Date:

- Guidance document for archiving of clinical research records for studies (June 2012)
- One clear and transparent clinical research administrative roadmap for the province (May 2012)
- Tools and templates for study budgeting (July 2012)

Strategic Priority 2

Promote Consistency in Legal Review Related to Clinical Research

STRATEGY Standardize legal review guidelines of contracts & agreements related to clinical research

Background:

Different institutional policies and procedures for contracts and confidentiality disclosure agreements require multiple agreements with different processes for the same study. A clear approach that ensures mitigation of legal and financial risks while streamlining the review process would lead to an integrated and efficient clinical research system in the province.

Actions Plans and Key Steps:

1. **Confidentiality Disclosure Agreement (CDA) resource template**
2. **Development of a model Clinical Trial Agreement (mCTA) in conjunction with Rx&D, the Canadian Institutes of Health Research (CIHR), and the Association of Canadian Academic Healthcare Organizations (ACAHO)**
   – Contribute to the development of national mCTA.
3. **Efficient signatory process for Clinical Trial Agreements (CTAs)**
   – Assess the existing policies to determine the required signatures.
4. **Coordinated contract negotiation for multi-centre industry-sponsored studies**
   – Outline the process for timely identification and notification of multi-centre studies between applicable institutions.
5. **Clarify flow of documents and communication between investigators and legal review departments**
   – Determine the required documents and steps, and expectations between investigators and legal reviewers.

Initial Milestones and Projected Development Date:

- Clear process and expectations outlined for contract submissions (August 2012)
- Development of a CDA resource template and outlined processes for use (July 2012)
- Efficient signatory process for Clinical Trial Agreements (October 2012)

Strategic Priority 3

Develop High Quality and Specialty Clinical Research Investigators and Staff

STRATEGY Develop provincial standards and opportunities for clinical research training

Background:

Currently, many institutions offer high quality clinical research training opportunities. Additionally, several individuals have developed expertise in specific diseases and populations, Good Clinical Practice (GCP), recruitment strategies, budgeting, study design and management, statistics, regulatory affairs, etc. The ACRC will leverage and create awareness of current training opportunities to improve the sharing of best practices and tools across the province. Through these actions, the ACRC will not only develop provincial standards for ongoing clinical research training, but also will build the capacity of qualified researchers and enhance the quality of clinical research.

Actions Plans and Key Steps:

1. **Coordinated pan-Alberta clinical research training program**
   - Define provincial standards, and leverage existing, or create as needed, clinical research courses that are or will be available province-wide
2. **Investigator-initiated study toolbox**
   - Outline the criteria and steps for investigator-initiated studies incorporating applicable regulations, resource links, and contacts
3. **Clinical research space for sharing of best practices, tools, resources, upcoming events and networking**
   - Develop regular newsletter that will outline events, changes in regulations, and education opportunities; and define the virtual space for networking, sharing of information, and resources

Initial Milestones and Projected Development Date:

- Provincial standards for Foundations of Clinical Research and Continuing Training (March 2012)
- Investigator-initiated study toolbox (July 2012)
- ACRC updates announcing events and sharing of best practice (July 2012)

Enabling ACRC Actions

Four enabling actions will be undertaken in support of the strategic priorities:

1. **Common terminology used across the province**

   Using the same terminology is an important starting point for developing clear, province-wide processes. The ACRC will work with various organizations in developing common terminology to avoid ambiguity.

2. **Communication strategy that effectively engages and informs individuals**

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

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. In order to improve efficiency and avoid duplication of work, the ACRC will assess what information should be collected and for what purpose, and facilitate this exchange of information as appropriate.

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

   To help support decision-making and reporting, the initiative and its strategic priorities will be evaluated and assessed individually and as a whole.

Next Steps and Timeline

Summer 2011

Draft strategic plan open for consultation.

Feedback incorporated for Executive Committee approval.

Sept - Dec 2011

Working Group created for each strategic priority consisting of individuals from across the province.

Working Groups developed plans with corresponding timelines and performance metrics for Executive Committee approval.

Jan – Dec 2012

Working Groups complete planning for implementation of the approved action plans and initiate implementation as appropriate.

- AIHS provides secretariat support, project management and coordination for ACRC activities.
- Updates on the initiative will be available on the AIHS website, or via newsletters and other mechanisms.

APPENDIX A:
Meeting Participants – May 30, 2011

Attendees:

- **Jennifer Barchard**, Covenant Health – Grey Nuns Hospital
- **Quincy Chu**, Alberta Health Services – Cross Cancer Institute/University of Alberta
- **Mary-Ann Clarkes**, Covenant Health
- **Sunil Desai**, Alberta Health Services – Stollery Children's Hospital/ University of Alberta
- **Derek Exner**, University of Calgary
- **Justin Ezekowitz**, University of Alberta
- **Konrad Fassbender**, University of Alberta
- **Richard Fedorak**, University of Alberta
- **Daniel Heng**, Alberta Health Services – Tom Baker Cancer Centre/University of Calgary
- **Michael Hill**, University of Calgary
- **Audrey Hollingshead**, Alberta Health Services - Red Deer Hospital
- **Shane Lacusta**, University of Calgary
- **Richard Leigh**, University of Calgary
- **John Mackey**, Alberta Health Services – Cross Cancer Institute/University of Alberta
- **Piush Mandhane**, University of Alberta
- **Carlos Miranda**, University of Alberta
- **Ian Mitchell**, University of Calgary
- **Sheli Murphy**, Covenant Health
- **Diana Shaw**, Covenant Health
- **Robert Sheldon**, Alberta Health Services
- **Rachel Syme**, Alberta Health Services
- **Robert Turner**, Alberta Health Services – Cross Cancer Institute/University of Alberta
- **Katia Tonkin**, Alberta Health Services – Cross Cancer Institute/University of Alberta
- **Clarence Weppler**, College of Physicians & Surgeons of Alberta
- **John Wong**, University of Calgary

For Alberta Innovates – Health Solutions:

- **Linda Barrett-Smith**, Director, Research Ethics and ACRC Initiatives
- **Jacques Magnan**, CEO
- **Tammy Mah-Fraser**, ACRC Project Manager
- **Pamela Valentine**, VP Programs
- **Yvonne Jackson**, Wetaskiwin Hospital & Care Centre (Recorder)
- **Pat Evans**, Patricia Evans & Associates. Inc., Vancouver BC (Facilitator)

APPENDIX B:
Stakeholders

This initiative involves a number of stakeholders. Below is the initial list of entities in the various stakeholder groups. The ACRC strives to work collaboratively and to align with a number of similar national and international initiatives.

Alberta Innovates (AI) Corporations
Bio Solutions
Energy & Environment Solutions
Health Solutions
Technology Futures

Funders
Canadian Institutes of Health Research
Canadian Health Services Research Foundation
Canadian Foundation for Innovation
National Sciences and Engineering Research
Canadian Agency for Drugs and Technologies in Health

Government
Federal:
- Health Canada
- Foreign Affairs & International Trade Canada

Provincial:
- Advanced Education and Technology
- Health and Wellness

Municipal:
- Cities in Alberta

Health Network
Primary Care 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
Covenant Health

Industry and Cooperative Groups
Children's Oncology Group, NCIC Clinical Trials Group, National Surgical Adjuvant Breast and Bowel Project (NSABP), Radiation Therapy Oncology Group (RTOG)

Pharmaceutical Companies
Rx&D

Patients and Public

Philanthropic Organizations
Provincial, National, and International
Alberta Cancer Foundation

Post-Secondary Institutions
University of Alberta
University of Calgary
University of Lethbridge
Research Ethics Boards
Alberta Cancer Research Ethics Committee (Alberta Health Services)
Research Ethics Review Committee (College of Physicians & Surgeons of Alberta)
University of Alberta Health Research Ethics Board (HREB) Panel A Biomedical Research and Panel B Health Research (University of Alberta)
Conjoint Health Research Ethics Board (University of Calgary)
Human Subject Research Committee (University of Lethbridge)
Community Research Ethics Board of Alberta (CREBA), Alberta Innovates – Health Solutions

Research Networks/Alliances
Provincial, National, and International

Research Administrative Units
Alberta Cancer Clinical Research Unit
Calgary Centre for Clinical Research
Covenant Health Research Centre
Northern Alberta Clinical Trials and Research Centre

Researchers and Research Staff

APPENDIX C:
Barriers and Enablers

Participants divided into breakout groups to answer two questions. Their answers are categorized into key themes below:

Q1. What are the barriers to creating a more positive and productive climate for clinical research in Alberta?

- Insufficient funding and resources to conduct clinical research
- Lack of standardization
- Fragmented and unclear administrative processes
- No incentive for innovation or to conduct clinical research
- Increasing regulatory environment
- Unclear provincial support
- Differences in conducting metropolitan versus rural research
- Separation of clinical and research processes
- Lack of communication and advocacy channels
- Changing clinical trials environment

Q2. What are the enablers or assets that can be leveraged to create a more positive and productive climate for clinical research in Alberta?

- World class clinical researchers, established relationships, and structure
- Alberta-wide health system
- Established clinical research infrastructure
- Motivated participants and researchers
- Value of research
- Available funding
- Timeliness for change
- Success of other models

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