REB EXCHANGE
RESEARCH TO RESULTS – FASTER.

YEAR 1 REPORT
2022

André Buret
Associate Vice-President (Research) and Professor of Biological Sciences, Faculty of Science, University of Calgary
A VISION

FOR ALBERTA, AND BEYOND.

During the last few turbulent years, research teams and institutions have recognized more than ever the need to stay connected. Multi-site studies have the potential for better data outcomes and are advantageous for all health research, including clinical trials. However, navigating the traditional ethics application process – which involves collecting and managing complex documentation requirements for submission – poses many challenges for researchers and administrators alike. So we find ourselves asking:

How can we be more effective and efficient? How can we establish and maintain collaborations with investigators close to home and afar? And how can we make our efforts go further and our findings reach more people?

Last spring, Alberta successfully launched the Research Ethics Board Exchange (REBX); a digital tool allowing for a collaborative approach to multi-site studies. REBX has been designed with prompts and triggers which significantly reduce the time and challenges traditionally experienced by sites who wish to participate in a study. Sites can even use their own REB systems without having to learn or adopt the Lead site’s.

Most importantly, this advancement will greatly facilitate approval and post-approval processes for any multi-site project, proving particularly valuable for clinical studies.

Over the past year the University of Calgary and the University of Alberta have used REBX to host over 220 sites conducting both clinical and non-clinical studies across 22 departments including pediatrics, clinical neurosciences, and nephrology making up over 60% of the overall use cases.

News of REBX’s success in Alberta is spreading and other provinces are beginning to take notice. In British Columbia, they are building their own provincial ethics harmonization processes, and the adaptability of the REBX makes it an attractive tool for Research Ethics British Columbia to implement. The flexibility of REBX to incorporate existing modules, like human resources, funding, biosafety and more, means future collaborators can join the network without sacrificing systems already in place.

As Alberta’s largest research institutions, the University of Calgary and the University of Alberta are leading by example to demonstrate the feasibility and benefits of true reciprocity in ethics for multi-site studies, through the trust and reliance on a single board of record, within and across provincial lines. We are very excited to see where REBX takes us over the next few years and how far the network has grown.

On the Cover:
Dr. André Buret, PhD, has been a key advocate for ethics harmonization practices in Alberta while spearheading the REBX project.
RESEARCH IN ALBERTA

CONNECTING THE DOTS

Alberta is a province with an eye on innovation and a goal of integration. We find ourselves at the precipice of a quiet revolution where technological solution-finding is front and centre in the quest to move beyond traditional and antiquated processes.

Alberta is Canada's fourth most populated province and home to more than 4 million people all served by a single, integrated health care system. While primarily English-speaking, the population is distinctly diverse with representation from all ethnic groups and 13% of residents belonging to a visible minority group.

More than 70% of Albertans live in urban areas, the majority within the Calgary-Edmonton corridor (one of the most densely populated areas in Canada). This positions much of the population close to major hospitals, medical centres, research sites, and academic institutes.

FORGING PATHWAYS

Alberta is home to some of the world’s most respected thought leaders across a range of therapeutic areas including cardiovascular health, oncology, rare diseases, and nervous system disorders.

Our province’s investigators are leading clinicians – highly trained and experienced at conducting clinical trials.

Housed within our collaborative network of academic institutions, hospitals, and medical research centres is an extensive range of cutting-edge labs and facilities.

Our province is home to a full spectrum of technologies including advanced imaging, biobanking, bioanalysis, and simulation faculties.

Strong government support and collaborative culture between academic institutions and public/private health resources has established Alberta as the place for conducting clinical trials.

Numerous initiatives have been introduced to increase patient recruitment, shorten start-up times, and reduce costs through competitive R&D tax incentives.

Complementing investigators is a highly trained workforce comprised of research coordinators, research associates for clinical trials, certified clinical research professionals, clinical research nurses, pharmacists, radiologists, and imaging technicians. A high number of masters and PhD graduates work in this sector, and adherence to best practices, including Good Clinical Practice (GCP), ensures data produced is accepted by major regulatory bodies.
Through integration, collaboration, and an established network of trust, Alberta is drawing the lines to help researchers navigate the resource ecosystem – efficiently and effectively.

**A DYNAMIC ECOSYSTEM TO CONDUCT HEALTH RESEARCH.**

Home to esteemed researchers working in an integrated and innovative research ecosystem, Alberta is a leading jurisdiction in health and clinical research.

Our recipe is unique: through the integration of world-class research centres, with a single health system under the Alberta Information Health Act, combined with access to entrepreneurial programs and innovation agencies, Alberta can offer researchers a real opportunity to generate impact in communities, both near and far.

**OVER 12,000 active studies in Alberta**

**WITH INVOLVEMENT FROM:**

- **A SINGLE PROVINCIAL HEALTH AUTHORITY**
  - Health Information Act of Alberta

- **PROVINCIAL HEALTH CUSTODIANS**
  - Alberta Health Services
  - Covenant Health

- **WORLD-CLASS RESEARCH INSTITUTIONS**
  - University of Calgary
  - University of Alberta

- **HEALTH RESEARCH ETHICS BOARDS**
  - Health Research Ethics Board of Alberta
  - Health Research Ethics Board (University of Alberta)
  - Conjoint Health Research Ethics Board (University of Calgary)

- **INNOVATION & ENTREPRENEURIAL RESOURCES**
  - Alberta Innovates
  - Innovate Calgary

- **COMMUNITY INVOLVEMENT**
  - Participate in Research (University of Calgary)
  - BeTheCure.ca

- **COMMITMENT TO CLINICAL TRIALS**
  - Clinical Trials Alberta
  - Northern Alberta Clinical Trials + Research Centre

- **PLATFORM PROVIDER**
  - Huron Consulting Inc.
THE REB EXCHANGE

MULTI-SITE RESEARCH SOLUTION –

REBX is an innovative technology platform that enables a single provincial ethics review for multi-site research conducted in Alberta.

By providing a centralized, singular point of submission, REBX reduces study costs and increases efficiency by helping to avoid duplication during the submission process, ensuring high quality reviews, and shortening study start-up times. It also allows for more efficient methods of reporting serious adverse events and reduces the need to engage multiple local research ethics boards.

Most importantly, REBX allows researchers to focus more time on conducting research by making study start-up at multiple sites more efficient.

In turn, communities can access and participate in more research studies across the province, including in smaller centres where researchers may not have access to established resources.

THAT BENEFITS ALL ALBERTANS.

IT ADAPTS TO YOU...

Just one full ethics application through your institution’s usual process and software. Once submitted, REBX uses behind-the-scenes hooks to seek relevant information from your ethics application and expedite additional site applications through a single board of record.

As soon as a study receives ethics approval, the researcher can use REBX to add a Participating Site (pSite) at any time with a click of a button integrated directly into your Research Ethics Board (REB) software. Then, once a pSite is added, the original study becomes the Lead Site.

- pSites receive an invitation to join the approved application through their own REB platform
- pSites submit only site-specific information and documents, reviewed by the Board of Record in the context of the already-approved ethics application
- Lead Sites can view all ethics documentation for all sites and receives notification of any pSite activity
- Allows custom workflows so you retain the power of your processes
- Incorporates both full and delegated board reviews that rely on involvement from all REBs in the network
- Modifications and reportable events are handled and expedited through the REBX
- All sites are included on the approval/renewal certificate and any modification / reportable event letters.
Adaptable workflows and scalable integrations connect systems using the software teams already use.
REBX: THE BENEFITS

SCALABLE INTEGRATIONS

Because REBX is an “add-on” to the software institutions currently use, it can be configured to seek information from different integrated systems to support the review and management process for funded or non-funded studies and trials. Integrations can include:

- Fund management
- Ethics review: human + animal
- Harmonization workflows
- Human resources
- COI + compliance
- Automations: notifications and logic systems
- Radiation + bio safety
- Extended reporting
- Affiliate institutions
  ... and more!

CUSTOMIZE WORKFLOWS

Lead sites can decide when pSites are added to the approved study and routed through the workflow without disrupting local pSite processes. This brand-new way of thinking about harmonization ensures local guidelines and legislation are always respected and retained.

ADAPTS AND EXCHANGES, EFFICIENTLY

At its core, REBX is a managed workflow that guides the researcher through the application process. It streamlines the sharing of information while reducing the administration work for research teams. Using hooks to identify key triggers, automations can be built to eliminate duplicate documentation and ensure consistency across sites.

STUDY SPONSORS

Institutions, partners, and industry sponsors (such as pharma, biotech, and medical device companies) will benefit from:

- Reduced administrative processes = faster start-up times = earlier results
- Streamlined collaboration between sites
- One REB of Record per study
- Simplified deployment of protocol modifications study-wide
- Documentation transferred to all sites
- Single renewal date for ethics across all sites
- Streamlined communication tools to deliver information and reporting for all sites

Ethics review fees are collected by the host institution for industry-sponsored studies (includes studies supported by any for-profit organization).

Each pSite added to an industry-sponsored study requires a one-time ethics fee.

Fees collected for industry-sponsored studies cover all renewals, modifications, reportable events, etc.
IMPACT
YEAR 1

224 SITES

FUNDING SOURCES
65
91% Grants
6% Contract
6% Internal Funds
3% Cooperative Groups
2% Other

FUNDING TYPES

35 AREAS OF STUDY GROUPS

67 AREAS OF STUDY

TIME TO DETERMINATION
By Review Type | Average In Days

ADMINISTRATIVE
3 days Administrative
8 days Researcher

ETHICS
3 days Ethics
8 days Researcher

ACTING BoR

52% UCalgary
48% UAlberta

221 FOLLOW-ON SUBMISSIONS
68% Study Amendments
20% Renewals/Closures
12% Reportable Events

3% Cooperative Groups
2% Other

22 DEPARTMENTS

Paediatrics
31%

Clinical Neurosciences
12%

Medicine
13%

Nephrology
9%

Surgery
4% ea.

Community Health Sciences
Family Medicine

Obstetrics & Gynaecology
Cardiac Science

Respiratory Medicine
Genetics
Nursing

Radiology
Kinesiology
Ophthalmology

Medicine - Education
Academic Programme
Academic Appointments

Physiology & Pharmacology
Pathology & Laboratory Medicine
Microbiology & Infectious Disease

Year 1 IMPACT

Respiratory Medicine
Genetics
Nursing
Kinesiology
Ophthalmology
Medicine - Education
Academic Programme
Academic Appointments
Paediatrics
Community Health Sciences
Family Medicine
Obstetrics & Gynaecology
Cardiac Science
Respiratory Medicine
Genetics
Nursing
Radiology
Kinesiology
Ophthalmology
Medicine - Education
Academic Programme
Academic Appointments
Physiology & Pharmacology
Pathology & Laboratory Medicine
Microbiology & Infectious Disease

FUNDING SOURCES
65
91% Grants
6% Contract
6% Internal Funds
3% Cooperative Groups
2% Other

FUNDING TYPES

35 AREAS OF STUDY GROUPS

67 AREAS OF STUDY

TIME TO DETERMINATION
By Review Type | Average In Days

ADMINISTRATIVE
3 days Administrative
8 days Researcher

ETHICS
3 days Ethics
8 days Researcher

ACTING BoR

52% UCalgary
48% UAlberta

221 FOLLOW-ON SUBMISSIONS
68% Study Amendments
20% Renewals/Closures
12% Reportable Events

3% Cooperative Groups
2% Other

22 DEPARTMENTS

Paediatrics
31%

Clinical Neurosciences
12%

Medicine
13%

Nephrology
9%

Surgery
4% ea.

Community Health Sciences
Family Medicine

Obstetrics & Gynaecology
Cardiac Science

Respiratory Medicine
Genetics
Nursing

Radiology
Kinesiology
Ophthalmology

Medicine - Education
Academic Programme
Academic Appointments

Physiology & Pharmacology
Pathology & Laboratory Medicine
Microbiology & Infectious Disease

Year 1 IMPACT

Respiratory Medicine
Genetics
Nursing
Kinesiology
Ophthalmology
Medicine - Education
Academic Programme
Academic Appointments
Paediatrics
Community Health Sciences
Family Medicine
Obstetrics & Gynaecology
Cardiac Science
Respiratory Medicine
Genetics
Nursing
Radiology
Kinesiology
Ophthalmology
Medicine - Education
Academic Programme
Academic Appointments
Physiology & Pharmacology
Pathology & Laboratory Medicine
Microbiology & Infectious Disease

FUNDING SOURCES
65
91% Grants
6% Contract
6% Internal Funds
3% Cooperative Groups
2% Other

FUNDING TYPES

35 AREAS OF STUDY GROUPS

67 AREAS OF STUDY

TIME TO DETERMINATION
By Review Type | Average In Days

ADMINISTRATIVE
3 days Administrative
8 days Researcher

ETHICS
3 days Ethics
8 days Researcher

ACTING BoR

52% UCalgary
48% UAlberta

221 FOLLOW-ON SUBMISSIONS
68% Study Amendments
20% Renewals/Closures
12% Reportable Events

3% Cooperative Groups
2% Other

22 DEPARTMENTS

Paediatrics
31%

Clinical Neurosciences
12%

Medicine
13%

Nephrology
9%

Surgery
4% ea.

Community Health Sciences
Family Medicine

Obstetrics & Gynaecology
Cardiac Science

Respiratory Medicine
Genetics
Nursing

Radiology
Kinesiology
Ophthalmology

Medicine - Education
Academic Programme
Academic Appointments

Physiology & Pharmacology
Pathology & Laboratory Medicine
Microbiology & Infectious Disease

Year 1 IMPACT

Respiratory Medicine
Genetics
Nursing
Kinesiology
Ophthalmology
Medicine - Education
Academic Programme
Academic Appointments
Paediatrics
Community Health Sciences
Family Medicine
Obstetrics & Gynaecology
Cardiac Science
Respiratory Medicine
Genetics
Nursing
Radiology
Kinesiology
Ophthalmology
Medicine - Education
Academic Programme
Academic Appointments
Physiology & Pharmacology
Pathology & Laboratory Medicine
Microbiology & Infectious Disease
Alberta hosts two prominent PERC sites: the Stollery Children’s Hospital in partnership with the University of Alberta’s Pediatric Emergency Advancing Knowledge (PEAK) team in Edmonton, and the Alberta Children’s Hospital in partnership with the University of Calgary’s Pediatric Emergency Research Team (PERT).

Together, these teams are collaborating and pushing for the best pediatric care possible through the creation and sharing of knowledge.

This goal was put to the test during the COVID-19 pandemic when little was yet known about how severely the disease would present in children and how long it could potentially take for vaccines to become available for the under-18 population.

By 2021, the virus had firmly established itself in the general population, and monitoring and testing was quickly overtaking health-care centres. Collection of test samples were generally conducted by a health-care professional in a controlled environment, with a nasal or throat swab without an issue – for most adults.

For children however, the goal posts needed to be widened. Due to the invasive nature of the nasal and throat swabs, the tests were difficult to administer, and knowing how quickly touch and airborne disease can spread among populations of children, an alternative solution needed to be explored.
“Our goal was to find another way of collecting samples that a non-health care trained parent or guardian could manage. We wanted to evaluate the diagnostic accuracy of a cheek swab, which would be easier and less painful to collect and could be done outside of a clinic or test centre,” explains Dr. Stephen Freedman, MD, professor of pediatrics and emergency medicine with the University of Calgary and principal investigator for the COVID-19 buccal swab study.

“We needed an answer to this question fast because the clock tends to tick faster during an outbreak.”

After teaming up with other PERC sites, including the Stollery Children’s Hospital in Edmonton, Dr. Freedman launched the PERC COVID-19 Buccal Swab Study which included a total of 15 sites across Canada.

“As the PI, my main concern was to launch the study expeditiously and a key element is obtaining ethics approval. This can be a huge factor impeding study launch, especially if we are conducting a study at multiple sites. Running this study through the REBX was extremely smooth and efficient with no challenges,” said Dr. Freedman when asked how REBX helped his team get the study off the ground when time was of the essence.

Dr. Bruce Wright, MD, physician and member of the University of Alberta’s PEAK team, led the team at the Stollery Hospital. “We’ve been stuck in this inefficient machine where regions and provinces are siloed – the wheels of the research cogs are off and the time is ripe for a new way of bringing ideas and findings together,” he says. “Being able to have the Alberta sites start the project at the same time through REBX was incredibly efficient and helped solidify collaboration when time was so crucial.”

Kelly Kim, project lead and research coordinator with the University of Calgary, worked closely with Dr. Freedman throughout the process. “Because this was a very time-sensitive study, going through the [REBX] really helped us be the first site to start recruitment,” she says. “And that means that for patients, we get our research question answered more rapidly which shortens the implementation of research findings into care.”

Efficiencies in the REB process allowed both the Calgary and Edmonton sites to be up and running a mere matter of weeks after submitting for approvals. This reduction in wait-times meant that pediatric patients in Alberta were able to benefit from this new sample collection method sooner and the monitoring of a vulnerable population could be scaled by administering the tests more easily.

When asked specifically about how she feels research is being regarded in Alberta, Kim adds, “there are really exciting things happening in the pediatric research community in Alberta and that’s great. We have been extremely successful with the studies that we conduct, including numerous Health Canada regulated trials involving novel therapeutic drugs and diagnostic devices.”

“And the other thing that’s quite important is we’re not just doing more studies, we are leading massive projects involving very large teams across the country and internationally. The fact we are heavily involved and leading many of these initiatives is a reflection of the importance placed on research in Alberta.”

Kelly Kim, project lead and research coordinator with the University of Calgary, worked closely with Dr. Freedman throughout the process. “Because this was a very time-sensitive study, going through the [REBX] really helped us be the first site to start recruitment,” she says. “And that means that for patients, we get our research question answered more rapidly which shortens the implementation of research findings into care.”

Efficiencies in the REB process allowed both the Calgary and Edmonton sites to be up and running a mere matter of weeks after submitting for approvals. This reduction in wait-times meant that pediatric patients in Alberta were able to benefit from this new sample collection method sooner and the monitoring of a vulnerable population could be scaled by administering the tests more easily.

When asked specifically about how she feels research is being regarded in Alberta, Kim adds, “there are really exciting things happening in the pediatric research community in Alberta and that’s great. We have been extremely successful with the studies that we conduct, including numerous Health Canada regulated trials involving novel therapeutic drugs and diagnostic devices.”

“And the other thing that’s quite important is we’re not just doing more studies, we are leading massive projects involving very large teams across the country and internationally. The fact we are heavily involved and leading many of these initiatives is a reflection of the importance placed on research in Alberta.”

>> Read more about the PERC Health Canada COVID-19 study here.
BETTER TOGETHER: STROKE RESEARCH IN ALBERTA

Stroke is a disease that affects approximately 100,000 Canadians over the age of 20 annually and the time-sensitive treatment decisions can have life-altering effects for the patient. Deprivation of the blood supply to a region of the brain due to an arterial blockage can result in the death of brain cells causing loss of speech, physical movement, vision, memory and more.

Alberta research teams are leading studies to make better treatment decisions in the critical moments through the use of clot-busting drugs for acute stroke. But they aren’t going at it alone – new processes are being used to bring health-care centres together across the province in new and exciting ways thanks to the REBX.

“Collaboration means better outcomes for patients in that more sites mean more diverse data and that leads to better outcomes,” says Dr. Michael Hill, MD, professor of neurology with the Calgary Stroke Program at the University of Calgary. “Not only can more sites participate when we reduce the barriers in the ethics process, but it also opens more avenues for funding as federal grants favour collaborative [multi-provincial] studies. It’s very clear that harmonization is the future of ethics processes and Alberta is right there at the forefront for pushing innovative solutions.”

Traditionally, due to the extensive administrative burden of participating in a multi-site study, the problem facing scientists and administrators has been figuring out how to make research available across Alberta in a way that makes clinical trials easier, less bureaucratic, and cheaper so that it positively impacts patients.

Enter REBX - with the help of this collaborative technology, small and rural sites can more easily participate in multi-site studies by reducing the administrative requirements and streamlining the ethics approval process through a single board of record.

This reduction in site-specific workload proved particularly relevant for the AcT Trial in which researchers wanted to study the effects of intravenous Alteplase compared to Tenecteplase treatments in patients with acute ischemic stroke. The goal was to run a large, multi-site trial with as large a sampling of patients as possible to build a more robust, and informed, treatment plan.

The three-year trial enrolled 700 patients in Alberta including Calgary, Edmonton, Medicine Hat and Red Deer as well as an additional 900 patients located elsewhere in Canada.

“The AcT Trial and REBX software together help remove barriers to accessing research while cutting administrative workload and benefiting patients,” says Dr. Bijoy Menon, MD, a professor of neurology at the Cumming School of Medicine and the Principal Investigator of the AcT Trial. “By improving access to high-end research for more sites, we are improving access to health care for more patients.”

“Smaller sites, like Grey Nuns in Alberta, may never have been able to participate without REBX due to the enormous administrative burden studies like this can have for teams navigating the ethics approval process on their own.” adds Dr. Brian Buck, MD, associate professor, Department of Medicine, Division of Neurology at the University of Alberta.

“Utilizing standardized approvals through a single Board of Record have huge cost and time savings – this is particularly critical in clinical trials where each site no longer has to do

SPOTLIGHT
independent reporting. With everything moving to electronic records, it makes so much more possible and only makes sense for us to combine forces.”

Things are moving swiftly for Canadian research and Alberta is at the helm pushing to bring research across the country together under cross-provincial reciprocity agreements. The fact that the REBX has been built in a modular structure not only allows for broad approvals with oversight across participating boards, but also allows for local and provincial guidelines to be incorporated.

Carol Kenney, RN, CCRP, Project Lead in the AcT Trial, says this study has highlighted the promise of REBX lessening the administrative workload for all involved, including nurses, while it expands research into more Alberta communities.

“It’s exciting that we are moving science forward,” says Kenney. “Patients in smaller centres can benefit by participating in trials of new devices and medications,” she says. “REBX has helped tremendously in managing the workload at sites such as Medicine Hat and Red Deer.”

With efficiencies that allow for recognition and trust between boards, we can effectively cut down the red tape in a responsible and efficient way, and put Canada on the map as leading innovative and collaborative approaches that ultimately benefit both patients and their families.

Dr. Brian Buck, MD, Associate Professor with the Department of Medicine, Division of Neurology at the University of Alberta

Dr. Michael Hill, MD, Professor of Neurology with the Calgary Stroke Program at the University of Calgary

>> The AcT trial is now closed with the results recently published in volume 400 of The Lancet.

“...It’s very clear that ‘integrated’ harmonization is the future of ethics processes.”
REB Exchange is a collaboration between Alberta institutions. The initiative is funded by Alberta Innovates, the University of Calgary, the University of Alberta, Huron Consulting, with in-kind contributions from Alberta Health Services, to collectively support research ethics harmonization in Alberta.